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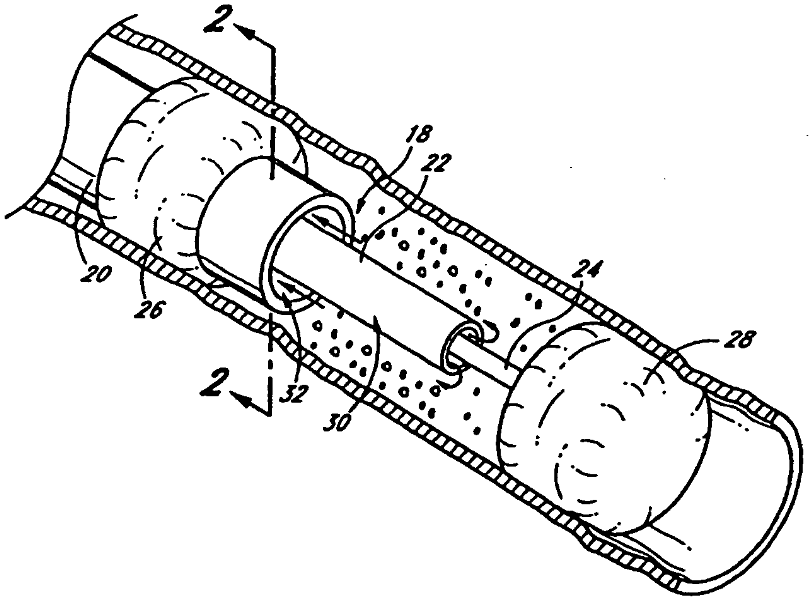

(57) Abstract

A multi-catheter (20, 22 and 24) emboli containment system is disclosed which is adapted to provide at least one pair of optimized paths (30 and 32) for irrigation and aspiration fluid flow. Through careful design of the cross-sectional area of these paths, the present system is able to be compactly utilized in even the smaller sized blood vessels. The catheter system itself is provided with occlusive devices (26 and 28) to form an emboli containment chamber in which irrigation and aspiration occur. The catheter system of the present invention provides an improved emboli containment and removal system which can be utilized in a wide range of vessel diameters. The system is easy to use and can quickly and efficiently evacuate the containment chamber.

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CATHETER SYSTEM FOR EMBOLI CONTAINMENT

Background of the Invention

Field of the Invention

The present invention relates generally to medical devices, and, in particular, to a system of improved irrigation and aspiration catheters used in the containment and removal of emboli resulting from therapeutic treatment of occlusions within blood vessels.

Description of Related Art

Human blood vessels often become occluded or blocked by plaque, thrombi, other deposits, or emboli which reduce the blood carrying capacity of the vessel. Should the blockage occur at a critical place in the circulatory system, serious and permanent injury, and even death, can occur. To prevent this, some form of medical intervention is usually performed when significant occlusion is detected.

Balloon angioplasty, and other transluminal medical treatments, are well-known, and have been proven efficacious in the treatment of stenotic lesions in blood vessels. The application of such medical procedure to certain blood vessels, however, has been limited, due to the risks associated with creation of emboli during the procedure. For example, angioplasty is not the currently preferred treatment for lesions in the carotid artery, because of the possibility of dislodging plaque from the lesion, which can enter the various arterial vessels of the brain and cause permanent brain damage. Instead, surgical procedures such as carotid endarterectomy are currently used, wherein the artery is split open and the blockage removed, but these procedures present substantial risks.

Other types of intervention for blocked vessels include atherectomy, deployment of stents, introduction of specific medication by infusion, and bypass surgery. Each of these methods are not without the risk of embolism caused by the dislodgement of the blocking material which then moves downstream. In addition, the size of the vessel may limit access to the vessel.

Thus, there is a need for a system to contain and remove such emboli. Various devices and methods have been proposed, but none have been especially commercially successful. Perhaps this is because a number of significant problems are faced in designing a system which will quickly and easily, yet effectively, evacuate emboli from a treatment location within a blood vessel. First, the small size of certain vessels in which such therapy occurs is a limiting factor in the design of emboli containment and removal systems. Vessels as small as 3 mm in diameter are quite commonly found in the coronary arteries, and even certain saphenous vein graph bypass vessels can also be as small as 3 mm or 4 mm; although some can range as high as 7 mm. Certain of the carotid arteries also can be as small as 4 mm in diameter; although, again, others are larger. Nevertheless, a successful emboli removal system must be effective within extremely small working areas. The system is equally effective in larger vessels, those of 5 mm or more in diameter.

Another obstacle is the wide variety in emboli dimensions. Although definitive studies are not available, it is believed that emboli may have approximate diameters ranging anywhere from tens of micrometers to a few hundred micrometers. More specifically, emboli which are considered dangerous to the patient may have diameters as large as 200 to 300 micrometers or even larger. Thus, an effective emboli removal system must be able to accommodate relatively large embolic particles and, at the same time, fit within relatively small vessels.

Another difficulty that must be overcome is the limited amount of time available to perform the emboli removal procedure. That is, it will be understood that in order to contain the emboli produced as a result of intravascular therapy, the vessel must be occluded, meaning that no blood perfuses through the vessel to the end organs. Although certain perfusion systems may exist or may be developed which would provide occlusion to emboli while permitting the substantial flow of blood, at present, the emboli may be contained only with a complete occlusion as to both blood flow and emboli escapement. Thus, again depending upon the end organ, the complete procedure, including time for the therapeutic treatment as well as exchanges of angioplastic balloons, stents, and the like, must be completed within just a few minutes. Thus, it would be difficult to include time for emboli removal as well. This is particularly true in the larger size vessels discussed above wherein a larger volume results in additional time required for emboli evacuation.

Moreover, it is important that an emboli containment and removal system be easy to use by physicians, and compatible with present therapeutic devices and methods. In addition, there are other difficulties which have made the successful commercialization of emboli containment and removal systems thus far virtually unobtainable.

Summary of the Invention

The present invention advantageously satisfies the need in the prior art by providing a catheter system adapted to provide at least one pair of optimized paths for irrigation and aspiration fluid flow. Through careful design of the cross-sectional area of these paths, the present system is able to be compactly utilized in even the smaller size blood vessels. It can also be easily adapted to provide efficient and speedy emboli containment and evacuation in larger size vessels. This system is compatible with more common therapy devices in widespread use today, and is designed for rapid evacuation and ease of use.

It will be appreciated that, as used herein, the term "catheter" is broadly used to refer to a number of medical instruments, including without limitation, guidewires, therapy catheters, and the like. Thus, it is important in the present invention that the medical instruments used therein cooperate together to define optimized paths for irrigation and aspiration, as set forth herein in more detail.

Thus, in one embodiment of the present system, at least two catheters are utilized to form and evacuate a treatment chamber. Again, however, it will be appreciated that the term "chamber" refers broadly to a treatment location or site where therapy is performed and emboli possibly produced. The catheters of the present invention telescope one in another in order to form a pair of irrigation and aspiration paths. An outer, larger diameter catheter forms the main body or housing for the system. An inner, smaller diameter catheter is positioned within the lumen of the outer or main catheter. An optional intermediate, or middle catheter is positioned over the inner catheter so as to be within the space formed between the inner and outer catheters. Thus, in this embodiment, the catheters cooperate to form two irrigation/aspiration paths: one between the outer catheter and intermediate catheter, and one between the intermediate catheter and inner catheter. In another embodiment, these paths are formed by the annulus between each pair of respective catheters of the present system; although it will be understood that, in use, the catheters may not necessarily be positioned concentric one with another. Therefore, the term "annulus" is used in a broader sense to refer to the path or space between any two catheters.

In addition, rather than being telescoped, the innermost two catheters may be placed side-by-side within the main catheter. In this embodiment, less frictional losses are experienced by the fluid as it flows in and out of the irrigation/aspiration paths. Moreover, the intermediate catheter may take the form of a dedicated irrigation catheter or, conversely, a dedicated aspiration catheter. Likewise, the intermediate catheter may comprise a therapy catheter which rides over the inner catheter (which itself may take the form as a typical guidewire) to the treatment site, or the therapy catheter can be built over an aspiration catheter to provide another embodiment of the intermediate catheter. Since irrigation or aspiration can take place in the path between the inner catheter and the therapy catheter, less time is incurred in the emboli removal process, since the therapy catheter need not be removed in exchange for other types of catheters.

Alternatively, the intermediate catheter can be a single main catheter configured to provide both irrigation and aspiration. This catheter has two lumens, one of which can extend past the distal end of the catheter. One lumen can be used to provide irrigation, while the other provides aspiration. This dual lumen catheter can be configured such that at least a portion of the catheter rides over the inner catheter. Alternatively, the catheter can comprise a rheolitic device, or any other device capable of both treating and aspirating the occlusion. This would eliminate the need for a separate aspiration catheter, thus simplifying the procedure.

In another embodiment, once therapy has been performed, the therapy catheter is removed, and the patient's own blood acts as irrigation fluid. This eliminates the need for a separate irrigation catheter and irrigation fluid. Aspiration can occur through an aspiration catheter, or through the outer catheter. This reduces the time necessary to complete the procedure and reduces the number of necessary catheters.

Another aspect of the present invention is that the catheter system itself is provided with occlusive devices to form an emboli containment chamber. It will be noted that at least two such occlusive devices are needed to form a chamber in a straight vessel, while multiple occlusive devices may be necessary to provide emboli containment in the case of a branching vessel. Again, in this context, the term "occlusive device" makes reference to the blocking or containment of emboli within the chamber, since perfusion systems which provide occlusion to the emboli are within the scope of the present invention. Thus, various types of occlusive devices such as filters or expandable braids that allow particles of less than 20 micrometers to pass through while preventing the passage of larger particles, and including inflatable or expendable balloons such as those which are employed by the present catheter system or otherwise, are within the scope of the present invention. In one preferred embodiment, the outer catheter comprises a main catheter having an occlusive balloon mounted on the outer diameter thereof. The occlusive balloon is inflated by means of an inflation lumen formed in a wall of the main catheter. The inner catheter comprises what may be referred to as a guidewire, but which is also hollow to provide an inflation lumen for a second occlusive balloon mounted at the distal section thereof. This occlusive balloon remains inflated until the guide catheter crosses the site of the lesion within the vessel. Thus, when inflated, these two occlusion balloons form an emboli containment chamber. The inner catheter provides a guidewire for those types of therapy devices which are in common use. One such catheter for a dedicated irrigation/aspiration catheter is positioned over the guidewire to form one of the irrigation/aspiration paths therewith.

Another advantage of the present invention is that the catheters are sized so as to optimize the cross-sectional area of the irrigation/aspiration paths. Thus, a larger range of emboli sizes are capable of being evacuated. Moreover, irrigation or aspiration is possible through either path, depending upon the desired conditions or particular procedure being performed. Thus, the versatility of the present system allows, in one embodiment, aspiration to be performed through the outer path and irrigation to be provided through the inner path, or vice versa. It will be noted for clarity that "outer path" refers to that formed between the outer catheter and the intermediate catheter, while "inner path" refers to that formed between the inner catheter and intermediate catheter.

In another embodiment, the respective irrigation/aspiration cross-sectional areas are designed to balance and optimize flow. This balancing of the path areas not only allows the reversal of irrigation or aspiration, as explained above, but also improves the fluid mechanics exhibited by the system. That is, the flow of irrigation fluid within the vessel can be analogized to fluid flow within a pipe, with the entrance of the pipe being the mouth of the irrigation catheter and the exit of the pipe being the mouth of the aspiration catheter; it is the flow into the chamber versus the flow out of the chamber that creates the pressure within the chamber. Thus, a differential in pressure at the mouths of the irrigation and aspiration catheters will generate a flow rate used to evacuate the containment chamber. However, since flow rate varies with the product of fluid velocity in the cross-sectional area, for steady flow rate, it would be observed that decreases in the cross-sectional area of one of the irrigation/aspiration paths will produce an increase in fluid velocity. Since local pressure varies with the square velocity, such a reduced path cross-sectional area could produce an excessive pressure which may damage the vessel. Thus, it is desirable that local pressures in the vessel not exceed about 1.5 atmospheres (e.g., less than about 50 psi). In addition to possible damage, excessive pressures may simply cause the vessel to expand without resulting in any advantageous increase in flow rate. Thus, by optimizing the respective areas of the irrigation/aspiration paths, these parameters can be maintained within tolerable limits.

Increases in internal or local pressures also require substantial increases in external pressures. That is, in order to maintain the desired flow rates necessary to quickly and efficiently evacuate the containment chamber, as the cross-sectional area of the irrigation/aspiration paths are reduced, a greater change in pressure (Δp) is required to generate sufficient fluid velocity. Taking into consideration the frictional losses in the system, extremely high Δp's may be required. Thus, it is important to maintain a balanced system so that excessive internal pressures are not produced, which may damage the vessel. Such pressures may also have the effect of causing a leak in the chamber.

Thus, the present invention provides a catheter system, comprising a hollow inner catheter having an occlusion device mounted on the distal end. At least a portion of an intermediate catheter is positioned over the inner catheter to create an inner fluid pathway for irrigation or aspiration. The intermediate catheter is slidable to a location proximal to the occlusion device on the inner catheter. A main catheter sized to receive the intermediate catheter such that an outer fluid pathway is formed therebetween for irrigation or aspiration. The main catheter also has an occlusion device mounted on its distal end which cooperates with the occlusion device on the inner catheter to form a chamber therebetween. The main catheter has an irrigation/aspiration port to permit irrigation or aspiration through its lumen. In one preferred embodiment, irrigation fluid is provided through the inner pathway and aspiration pressure is provided through the outer pathway.

The inner catheter is preferably a guidewire. The intermediate catheter can be an irrigation catheter, an aspiration catheter, a combined irrigation/aspiration catheter, or a therapy catheter, such as a drug delivery catheter, a laser, an ultrasound device, a thrombectomy catheter, a rheolitic device, a stent-deploying catheter, or any of a number of devices. The therapy catheter can be, for example, a balloon angioplasty catheter. Inflatable balloons can also be used as the occlusion devices on the inner and main catheters. To inflate the balloon, tne main catheter can further comprise an inflation lumen located in the wall of the catheter in fluid communication with the inflatable balloon. The intermediate catheter can have both a main lumen and a separate lumen adjacent the main lumen sized to received the inner catheter slidably therein. The separate lumen can have a slit in an outside wall for insertion and removal of the inner catheter therethrough.

To fit in small blood vessels, it is preferred that the main catheter has an outer diameter of less than 5 mm. To provide efficient clearance of the emboli containment chamber, the inner pathway and the outer pathway should have an opening at their distal ends which act to balance fluid flows. In preferred embodiments, the inner pathway and the outer pathway each have an opening allowing the passage of particles of about 20 micrometers, up to those at least about 500 micrometers in diameter.

The system can include at least one additional inner catheter having an occlusion device mounted on its distal end sized to fit slidably within the intermediate catheter. This system can be used within branching blood vessels where more than one branch must be occluded to create an isolated chamber.

Accordingly, the catheter system of the present invention provides an improved emboli containment and removal system which can be utilized in a wide range of vessel diameters, including extremely small ones. The system is easy to use and can quickly and efficiently evacuate the treatment chamber.

Brief Description of the Drawings

FIGURE 1 is a schematic illustration of the catheter system of the present invention illustrating the manner in which an emboli containment chamber is formed.

FIGURE 2 is a cross-sectional view taken along line 2-2 of FIGURE 1 illustrating schematically one embodiment of the irrigation and aspiration paths which are formed by the catheter system of present invention.

FIGURE 3 is a side view of the main catheter for use in the present invention.

FIGURE 4 is a cross-sectional view of the main catheter taken along line 4-4 of FIGURE 3.

FIGURE 5 is a cross-sectional view of the main catheter taken along line 5-5 of FIGURE 3.

FIGURE 6 is a side view of an over-the-wire irrigation or aspiration catheter for use in the present invention.

FIGURE 7 is a side view of a single operator irrigation catheter for use in the present invention.

FIGURES 8 through 10 are cross-sectional views of the single operator catheter taken along lines 8-8, 9-9 and 10-10 of FIGURE 7.

FIGURE 10A is a cross-sectional view of the single operator catheter inserted within the main catheter, illustrating schematically the inner and outer paths which are formed by the catheter system of present invention.

FIGURE 11 is a side view of an over-the-wire aspiration catheter for use in the present invention.

FIGURE 12 is a cross-sectional view of the over-the-wire aspiration catheter taken along line 12-12 in FIGURE 11.

FIGURE 13 is a cross-sectional view of the over-the-wire aspiration catheter taken along line 12-12 in FIGURE 11, showing a guidewire inserted therethrough.

FIGURE 14 is a side view of a single operator aspiration catheter for use in the present invention.

FIGURE 15 is a cross-sectional view of the single operator aspiration catheter taken along line 15-15 of FIGURE 14.

FIGURE 16 is a side view of an inner catheter for use in the present invention.

FIGURE 17 is a is a partial cross-sectional view of the inner catheter taken along line 17-17 of FIGURE 16.

FIGURES 18A-H illustrate the use of the catheters of the present invention in emboli containment treatment procedures.

FIGURE 19 is a graph illustrating the exponential trend of fluid flow versus pressure in the emboli containment chamber.

FIGURE 20 is a graph illustrating the effect of irrigation and aspiration pressures on flow rate within the emboli containment chamber.

Detailed Description of the Preferred Embodiment

The present invention provides a system of improved irrigation and aspiration catheters used in the treatment of occlusions within blood vessels and emboli containment. The apparatus of the present invention are adapted for use in the treatment of an occlusion in a blood vessel in which the occlusion has a length and a width or thickness which at least partially occludes the vessel's lumen. It is to be understood that "occlusion" as used herein, includes both complete and partial occlusions, stenoses, emboli, thrombi, plaque, and any other substance which at least partially occludes the lumen of the blood vessel.

Emboli Containment and Removal

Referring to FIGURE 1, there is shown a schematic illustration of the catheter system of the present invention and the manner in which it forms an emboli containment chamber for efficient emboli removal. The catheter system, in this embodiment, comprises a three-catheter system, including an outer or main catheter 20, an intermediate catheter 22, and an inner or guidewire catheter 24. This catheter system is shown schematically inserted within a relatively small vessel having a diameter d. As set forth above, the diameter d of the vessel may be as small 3 mm to 4 mm; although the present system can be efficiently utilized within vessels of larger diameter. An emboli containment chamber is formed between the outer 20 and inner 24 catheters, each of which in the preferred embodiment are provided with inflatable occlusion balloons 26 and 28. As noted above, the present invention is compatible with other types of occlusive devices, including those which permit perfusion and those which have other deployment mechanisms, such as filters, braids and the like. The present system is also compatible with containment chambers of variable length. Chambers of longer lengths contain a large volume of fluid and, thus, increase the time for emboli evacuation and/or increase the pressure differential (Δp) required to achieve desirable evacuation flow rates. Thus, containment chambers in the range of about 0.3 cc to 30 cc are preferable.

Although FIGURE 1 illustrates the present catheter system deployed within a straight vessel, it will be understood that the principles of the present invention also include other vessel configurations, including branches vessels. In such cases, a third or even additional occlusive devices may be used in order to contain the emboli and form a working chamber. Such occlusive devices could be mounted on additional inner catheters similar to the one illustrated in FIGURE 1, or on a single inner catheter having itself two branches, or otherwise. FIGURE 1 illustrates an important feature of the present invention in which the catheters 20, 22, 24 are telescoped within one another. Thus, the inner catheter 24 is relatively small in outer diameter and fits within the inner diameter of the intermediate catheter 22 and can, in some applications, serve as a guidewire therefor. Likewise, the outer diameter of the intermediate catheter 22 fits within the inner diameter of the outer or main catheter 20. The catheters 20, 22, and 24 thus form inner and outer pathways, 30 and 32 between the inner 24 and intermediate 22 catheters and the intermediate 22 and outer 24 catheters, respectively. It is through these pathways 30, 32 that irrigation or aspiration may be performed. Advantageously, in the present system, irrigation can be performed through the inner pathway 30 and aspiration through the outer pathway 32, or vice versa. As explained below in more detail, irrigation refers to the injection of fluid through one of the pathways into the containment chamber in order to generate an evacuation flow rate. Fluid, together with emboli, are evacuated through the other pathway, being assisted by the aspiration pressure which is in reality a suction or negative pressure. It is this pressure differential over some length within the chamber which generates the evacuation fluid flow.

As merely one example, irrigation fluid could be supplied at one pressure through the irrigation pathway as indicated by the small arrows in FIGURE 1. Due to the pressure differential in the chamber, fluid begins to flow toward the outer pathway, being assisted by the negative aspiration pressure. Thus, emboli in the chamber are swept through the outer pathway indicated by the arrows. Accordingly, FIGURE 1 illustrates one catheter arrangement of the present invention in which the catheters 20, 22, 24 are telescoped one inside the other; although the principles of the present invention apply equally well to other nontelescoped catheter configurations. Also, as noted above, other types of catheters may be used in connection with the present system. FIGURE 2 illustrates a cross-sectional view of the present catheter system taken along lines 2-2 of FIGURE 1, and illustrates in further detail relative cross-sectional dimensions of the inner and outer pathways. However, it will be noted that FIGURE 2 is schematic in the sense that it illustrates the inner 24 and intermediate 22 catheters positioned at the bottom of the lumen of the outer catheter 20. This is for ease of illustration only, as it will be understood that in actual practice the positions of the various catheters 20, 22, 24, relative one to another may vary due to pressures, flow rates, etc. The catheters 20, 22, 24 of the present system are designed so as to compactly fit within even small diameter vessels and at the same time optimize the cross-sectional areas of the inner and outer pathways. This design criteria, for a given flow rate, can be expressed as follows:

$$Q = \frac{Dp\pi d^4}{128L\mu}$$

where: Q - flow rate

Dp - pressure differential between the proximal and distal ends of the catheter

D - net diameter of the catheter

L - the overall length of the catheter

μ - the viscosity of the fluid

128 - constant factor

Thus, when a particular desired flow rate is known, the foregoing equation can be solved for D to give an optimized inner diameter of the intermediate catheter 22 when empty, or an equivalent diameter when the inner diameter is partially occluded by, for example, the inner catheter. It will be noted that the diameter of the intermediate catheter 22 is perhaps the more sensitive design parameter since, as it increases or decreases the cross-sectional areas of the inner and outer pathways increases and decrease, respectively. Furthermore, the other parameters in the equation are often given, including the external pressure differential, the length of the intermediate catheter 22 (which is typically about 100-120 cm) and the viscosity of the fluid. As for the desired flow rate, it will be understood that merely one flushing of the containment chamber may not be sufficient to remove all emboli. This is because of the relatively high viscosity of the patient's blood in the chamber and the inertia of the emboli which must be overcome. Also, as set forth above, some emboli are relatively large in diameter requiring several flushes. Thus, preferably, the flow rate will be such that the fluid in the containment chamber is changed at least about twice within a two- or three-minute period, while maintaining the local pressure in the chamber within a safe range (less than about 50 psi). Preferably, the fluid will be changed as many as five times or more within a minute in order to reduce the overall treatment time in connection with these procedures.

It will be understood that Figure 2 illustrates an ideal condition in which size of the openings of the inner and outer pathways are maximized. As this illustration does not always represent actual conditions, emboli size must be taken into consideration. Thus, the maximized opening for the inner and outer pathways (ip_m and op_m) should be at least about 150 micrometers and more preferably about 1000 micrometers. Thus, in the minimum state, where all of the catheters 20, 22, 24 are approximately concentric with one another, ip_m and op_m will range between about 250 and 500 micrometers. Thus, good evacuation performance should still be attainable.

In one embodiment of the present system, described below in more detail in connection with an irrigation and aspiration study, a catheter system found to be suitable comprised an outer catheter 20 with an inner diameter of .086" and an intermediate catheter 22 with inner and outer diameters of .048" and .054", respectively. The inner catheter 24 comprises a guidewire of typical outer diameter of about .014" but can be as large as .038".

Converting these dimensions to micrometers yields a total inner diameter of the outer catheter 20 of about 2200 micrometers, an outer diameter of the inner catheter 24 of about 355 micrometers, and a wall thickness of the intermediate catheter 22 of about 150 micrometers. This leaves a maximum inner pathway opening (ip_m) of about 770 micrometers and the maximum outer pathway opening (op_m) of about 800 micrometers. This will be sufficient to remove even larger sized emboli. This example also illustrates a catheter system configuration in which the respective cross-sectional areas of the inner and outer pathways are similar, thus yielding a balanced pressure differential condition in the containment chamber. By eliminating the use of the intermediate catheter, as explained below, the opening of the outer pathway can be increased even more.

Catheter Construction

Outer Catheter

FIGURE 3 illustrates a side view of a catheter which can be used as the outer catheter of the present system. Catheter 110 generally comprises an elongate flexible tubular body 116 extending between a proximal control end 112 and a distal functional end 114. The tubular body 116 has a main lumen 130 which extends between the ends 112 and 114. The main lumen 130 terminates in a proximal opening 123 and a distal opening 127. A smaller inflation lumen 132, configured in a side-by-side relationship with the main lumen 130, extends along the length of the tubular body 116, and terminates within an occlusion balloon 126 mounted on the distal end 114 of the catheter 110, as described below. The inflation lumen 132 is in fluid communication with the occlusion balloon 126, such that fluid passing through the inflation lumen 132 may be used to inflate or deflate the balloon 126. The infaltion lumen can terminate at its proximal end at one of the ports 122, 124 on the catheter 110.

The tubular body 116 must have sufficient structural integrity, or "stiffness," to permit catheter 110 to be advanced through vasculature to distal arterial locations without buckling or undesirable bending of tubular body 116. However, it is also desirable for tubular body 116 to be fairly flexible near its distal end 114, so that the tubular body 116 may be navigated through tortuous blood vessel networks. Thus, in one preferred embodiment, the body 116 is made to have variable stiffness along its length, with the proximal portion of the body 116 being less flexible than the distal portion of the body 116. Advantageously, a tubular body 116 of this construction enables a clinician to more easily insert the catheter into blood vessel networks difficult to reach by catheters having uniform stiffness. This is because the stiffer proximal portion provides the requisite structural integrity needed to advance the tubular body 116 without buckling, while the more flexible distal region is more easily advanced into and through tortuous blood vessel passageways.

In one preferred embodiment, variable stiffness along the length of the tubular body 116 is achieved by forming a polymeric tubular body 116 which incorporates a reinforcement along its length. Such reinforcement can be a braid or coil formed of various metals or polymers. The body 116 may be provided with a reinforcement incorporated into its wall structure. To achieve variable stiffness, the proximal region of the catheter 110 can be provided with greater reinforcement than the distal region.

The precise density of the braiding or pitch of the coil provided to the proximal and distal regions can be varied considerably at the point of manufacture, such that catheters having a variety of different flexibility profiles may be created. Moreover, the braid density or coil pitch may be varied within the various catheter regions, by providing a reinforcement that has a density or pitch gradient along its length.

A variety of different materials, known to be ductile and shapeable into fine wires, may be used to form the reinforcement, such as various polymers, stainless steel, gold or silver plated stainless steel, ELGILOY, platinum or nitinol. The reinforcement may be introduced into the structure of the catheter body 116 through conventional catheter forming techniques. Moreover, any of a variety of different polymeric materials known by those of skill in the art to be suitable for catheter body manufacture may be used to form the tubular body 116. Different materials might also be combined to select for desirable flexibility properties.

Also, although the tubular body 116 has been described in the context of having two regions of differing flexibility, it will be readily appreciated by those of skill in the art that three or more regions of differing flexibility may easily be provided, by adapting the teachings contained herein.

A control manifold 119 is provided at the proximal end 112 of the catheter 110. The control manifold 119 is generally provided with a number of ports to provide access to the catheter lumen 130. For example, for the embodiment depicted in FIGURE 3, the control manifold 119 is provided with a catheter end-access port 122 and a catheter side-access port 124, to provide an introduction point for the insertion of other catheters into the lumen 130. Ports 122 and 124 are preferably provided with standard Touhy Borst connectors, although other types of connectors may be used. An inflation port 118, in fluid communication with the small inflation lumen 132, is further provided on the manifold 119 for attachment of devices to inflate or deflate the balloon 126. The manifold 119 is also provided with an irrigation/aspiration port 120 which is in fluid communication with the lumen 130, for attachment of devices to provide irrigation fluid or aspiration pressure. Other embodiments of the main catheter 110 may feature more or less ports, depending upon the number of lumen in the catheter and the desired functionalities of the catheter.

The manifold 119 is preferably formed out of hard polymers or metals, which possess the requisite structural integrity to provide a functional access port to the catheter lumen, such as for balloon inflation or delivery of irrigation fluid and/or aspiration pressure. In one preferred embodiment, the manifold 119 is integrally formed out of polycarbonate. Of course, any suitable material may be used to form the manifold 119.

The manifold 119 is attached to the tubular body 116 so that the various ports are placed in communication with the appropriate lumen, as described above in connection with FIGURE 3. Preferably, a strain relieving connector 111 is used to join the manifold 119 to the tubular body 116. For the embodiment depicted in FIGURE 3, the strain relieving connector 111 consists of a length of flexible polymeric tubing, such as polyethylene terephthalate (PET). The tubular body 116 is inserted in one end of the strain relieving connector 111, and the other end of the strain relieving connector 111 is inserted into the manifold 119. A suitable adhesive, such as a cyanoacrylate, may be used to bond the manifold 119 to the strain relieving connector 111. Adhesives may also be used to bond the strain relieving connector 111 to the tubular body 116, or alternately, conventional heat bonding, as known to those of skill in the art, may be used to attach the tubular body 116 to the strain relieving connector 111.

Although not required, the interior surface of the lumen 130 may be provided with a liner 135 formed of a lubricous material, to reduce the frictional forces between the lumen surface and the catheters which are inserted into the lumen 130. In one preferred embodiment, the liner 135 is formed out of polytetrafluoroethylene (PTFE). Materials other than PTFE, which are biocompatible, fairly flexible, and easily mounted to other polymeric materials of the type used to form catheter tubular bodies, may also be used to form the liner 135.

To minimize the outer diameter of the tubular body 116, it is preferable that the inflation lumen 132 be as small as possible in accordance with its function. That is, the inflation lumen 132 is preferably no larger than required to provide sufficient fluid to the occlusion balloon 126 for rapid inflation, or so that fluid may be quickly withdrawn from the balloon 126 during deflation. For compliant expansion balloons of the type described below, inflation lumen diameters of from about .006 inches to about .020 inches are satisfactory, with a diameter of about .010 inches being optimal.

Furthermore, in one embodiment, as illustrated in FIGURES 3-5, the outer diameter of the tubular body 116 just proximal to the balloon 126 is minimized by providing an inflation lumen 132a with an oval cross-sectional configuration, as illustrated in FIGURE 5. Preferably, this inflation lumen 132a has an oval cross-sectional configuration which extends proximally from the proximal end of the balloon 126 by a distance of at least 0.1 cm, more preferably 1 cm, and optimally by a distance equal to the length of the tubular body. For ease of manufacturing, the cross-sectional configuration of the lumen 132 at points further proximal to the balloon 126 may be generally circular, as illustrated in FIGURE 4. Where the lumen configuration differs from proximal to distal end, as illustrated in FIGURES 4 and 5, a region of transition 133 is provided wherein the lumen configuration changes from circular to oval.

As illustrated in FIGURE 3, an inflatable balloon 126 is mounted on the distal end 114 of the catheter 110. In most applications where the catheter 110 is to be used in an emboli containment treatment procedure, the inflatable balloon 126 will function as an occlusion balloon, to prevent blood from passing through the blood vessel distal of the balloon 126. Thus, the inflatable balloon 126 is preferably able to expand to fit a variety of different blood vessel diameters. Accordingly, it is preferred that the inflatable balloon 126 have a compliant expansion profile, tending to increase in radial diameter with increasing inflation pressure. To achieve this, the balloon 126 may be made out of materials which impart such expansion characteristics, including elastomeric materials such as latex or irradiated polyethylene. In one preferred embodiment, the inflatable balloon 126 is formed out of a material comprising a block copolymer of styrene-ethylene-butylene-styrene, sold under the trade name C-FLEX.

The inflatable balloon 126 can be placed in fluid communication with the lumen 132a via a fill hole (not shown) extending through the tubular body 116 within the balloon 126, such that fluid may be introduced into the lumen 132 through an inflation port 118 to inflate the balloon 126. Alternately, the lumen 132a may terminate within the balloon 126, to provide the requisite fluid communication. The balloon 126 may be attached to the tubular body 116 by any suitable manner known to those of skill in the art, such as adhesives or heat bonding.

Intermediate Catheter

FIGURE 6 is a side view of an irrigation or aspiration catheter 140 which may be utilized as the intermediate catheter. It should be understood that when an irrigation catheter is used for the intermediate catheter, aspiration occurs through the outer pathway between the intermediate and main catheters, while irrigation occurs through the inner pathway. When an aspiration catheter is used as the intermediate catheter, aspiration occurs through the inner pathway between the intermediate and main catheters, while irrigation occurs through the outer pathway. Irrigation fluid under pressure is supplied at the proximal end of the catheter 142 and delivered into the containment chamber through the side holes 146 and through the distal end of the chamber 144. Alternatively, aspiration or negative pressure can be provided at the proximal end of the catheter 142 and fluid and debris aspirated through the side holes 146 and the distal end of the catheter 144. The catheter 140 may be about 125 cm in length and constructed from a plastic material such as HYTREL tubing, high density polyethylene (HDPE) or PEBAX (Atochem, France). In order to achieve a softer distal section, the durometer of the tube 148 material is reduced in that area to about 55 whereas that of the proximal section 142 is higher, such as about 80. The distal opening is preferably about .040", and the outer diameter is preferably about .065". Proximal valves and fittings which are well known in the art can be mounted on the irrigation catheter 140 of FIGURE 6. This catheter can be of either over-the-wire (as shown) or single operator design, as explained in more detail below.

FIGURES 7-10 illustrate another type of irrigation or aspiration catheter 230 which can be used as the intermediate catheter of the present system. In the case of the irrigation catheter, irrigation is through the inner pathway and aspiration is through the outer pathway. If the catheter is used for aspiration, aspiration is through the inner pathway and irrigation is through the outer pathway. As shown in FIGURES 7-10, the catheter 230 has an adaptor 232 on its proximal end. This single operator catheter 230 further comprises a long tubular body 236 having a distal end 238. The distal tip 238 can include a radiopaque marker to aid in locating the tip 238 during insertion into the patient, and is preferably soft to prevent damage to the patient's vasculature. At the distal end of the shaft 238, an inner catheter lumen 240 is attached. This lumen 240 provides a separate lumen, apart from the main lumen 242 of the catheter 230, for the insertion of the inner catheter. The inner diameter of the inner catheter lumen ranges from about .016" to about .020" for use with a .014" inner catheter system. In a preferred embodiment, the inner diameter of the lumen is about .019 in. This inner catheter or guidewire lumen can be as short as 5 cm, but can extend 30 cm or longer in a proximal direction. During delivery of the catheter 230, the proximal end of the inner catheter is inserted into the distal end of the inner catheter lumen 240, and the lumen 240 is slidably advanced over the inner catheter. Only a short segment of the single operator catheter 230 rides over the inner catheter, and the inner catheter remains in the lumen 240 and does not enter the main lumen 242 of the catheter 230.

Although the inner catheter lumen 240 is shown in FIGURE 7 as being located only on the distal end 238 of the shaft of the catheter 236, the lumen 240 can also be made to extend the entire length of the shaft 236 if desired. In both embodiments, the main lumen 242 is advantageously left completely unobstructed to provide more efficient irrigation or aspiration. The inner catheter lumen 240 can also include a slit 241 or weakened area in the outside wall of the lumen 240 along the entire length of the lumen 240 to facilitate faster and easier insertion and removal of the inner catheter through the side wall of the lumen 240. By inserting and removing the inner catheter through the side wall of the lumen 240 on the catheter 236, the need to remove adapters and attachments from the proximal end prior to slidably advancing or removing the catheter 236 over the inner catheter is eliminated. It should be understood that this slit 241 or weakened area through which the inner catheter can be inserted and removed can exist on the intermediate catheter regardless of whether the catheter is used for irrigation, aspiration, therapy or some other purpose.

FIGURE 10A is a cross-sectional view of a single operator intermediate catheter 252 positioned within the main catheter 250. The separate lumen 254 adapted to receive the inner catheter is positioned adjacent the lumen of the intermediate catheter 252. It should be understood that this positioning will occur when any single operator intermediate catheter is used. FIGURE 10A illustrates schematically the inner (IP) and outer pathways (OP) for irrigation and aspiration which are formed by the catheter system of the present invention when a single operator intermediate catheter is used.

Another embodiment of an aspiration catheter suited for use as the intermediate catheter in the present invention is illustrated in FIGURES 11-13. The catheter 260 includes an adaptor 262, preferably a female luer adaptor, at its proximal end. The catheter 260 further includes an aspiration port 264 to which a source of negative pressure is attached. The aspiration catheter further comprises a long tubular body 266 having a distal end 268. The distal tip 268 can include a radiopaque marker to aid in locating the tip 268 during insertion into the patient, and is preferably soft to prevent damage to the patient's vasculature. The aspiration catheter is preferably about 145 cm in length, although this length can be varied as desired.

As seen in FIGURE 12, the catheter body 266 is hollow, with an internal diameter ranging from about .020" to about .050". Preferably, the inner diameter is about .045". During insertion of the aspiration catheter 260, the proximal end of the inner catheter 270 is inserted into the distal end of the aspiration catheter 268, and the aspiration catheter 260 is slidably advanced over the inner catheter 270, which is positioned inside the hollow lumen 272 of the aspiration catheter 260. The position of the inner catheter 270 relative to the body of the aspiration catheter 266 is illustrated in FIGURE 13, but of course, can vary. For this type of aspiration catheter 260, a very long inner catheter 270, generally around 300 cm in length, is used to facilitate the insertion of the aspiration catheter 260.

FIGURES 14-15 illustrate another embodiment of an aspiration catheter 250 suitable for use as an intermediate catheter in the present invention. This catheter 280 comprises an elongate shaft 282 with a lumen 284 for aspiration. At the distal end 288, a separate inner catheter lumen 286 is positioned adjacent the main aspiration lumen 284. Again, this lumen 286 provides a separate lumen, apart from the main lumen 284 of the catheter 280, for the insertion of the inner catheter. This inner catheter or guidewire lumen 286 can be as short as 5 cm, but can extend 30 cm or longer in a proximal direction. During delivery of the single operator aspiration catheter 280, the proximal end of the inner catheter is inserted into the distal end of the inner catheter lumen 286, and the lumen 286 is slidably advanced over the inner catheter. Only a short segment of the single operator aspiration catheter 280 rides over the inner catheter, and the inner catheter remains in the lumen 286 and does not enter the aspiration lumen 284 of the catheter 280. Again, the lumen 286 can have a slit (not shown) or weakened area in a side wall to facilitate insertion and/or removal of the inner catheter through the side wall of the lumen.

If desired, a rheolitic device such as the ANGIOJET thrombectomy catheter available from Possis Medical Inc., Minneapolis MN can be used. This device acts as both a therapy catheter and an irrigation/aspiration catheter. The device breaks up the thrombus or other occlusion and removes it. This eliminates the need to provide separate catheters for these functions. Thus, the term "aspiration catheter" includes rheolitic devices, thrombectomy devices and any device which creates an area of fluid turbulence and uses negative pressure to aspirate fluid and debris, and includes devices which create a venturi effect within the vessel.

Alternatively, a single catheter having two separate lumens can be used to provide both irrigation and aspiration. The dual lumen catheter can be configured to be over-the-wire, or of single operator design. Preferably, one lumen extends past the distal end of the catheter so that the opening of one lumen is spaced some distance apart from the opening of the second lumen. Thus, irrigation occurs some distance away from aspiration.

In another embodiment, a combined aspiration/therapy catheter can be used. For example, an angioplasty balloon can be attached to the distal end of an aspiration catheter. Alternatively, the aspiration catheter can be designed to deploy a stent within the occluded vessel, or the catheter could include an atherectomy device on its distal end. The aspiration and therapy devices are therefore delivered into the blood vessel together.

In the catheters of the present invention, the elongate catheter shaft must have sufficient structural integrity, or "stiffness," to permit the catheter to be pushed through the vasculature to distal arterial locations without buckling or undesirable bending of the body. It is also desirable, however, for the catheter body to be fairly flexible near its distal end, so that the tubular body may be navigated through tortuous blood vessel networks. Thus, the tubular body of the catheter can be formed from a polymer such as polyethylene, or PEBAX made to have variable stiffness along its length, with the proximal portion of the tubular body being less flexible than the distal portion of the body. Advantageously, a tubular body of this construction enables a user to more easily insert the tubular body into vascular networks difficult to access using conventional catheters of uniform stiffness. This is because the stiffer proximal portion provides the requisite structural integrity needed to advance the catheter without buckling, while the more flexible distal region is more easily advanced into and through tortuous blood vessel passageways.

Inner Catheter

As shown in FIGURES 16-17, the inner catheter apparatus 310 can generally be comprised of four communicating members including an elongated tubular member 314, a balloon member 316 and a core-wire member 320 and a coil member 322. The catheter apparatus 310 is preferably provided with an outer coating of a lubricous material, such as TEFLON.

The body tubular member 314 of the catheter apparatus 310 is in the form of hypotubing and is provided with proximal and distal ends 314A and 314B and as well as an inner lumen 315 extending along the tubular member 314. The balloon member 316 is coaxially mounted on the distal end 314B of the tubular member 314 by suitable adhesives 319 at a proximal end 316A and a distal end 316B of the balloon member 316 as in the manner shown in FIGURE 17. The core-wire member 320 of the catheter 310 may be comprised of a flexible wire 320. The flexible wire 320 is joined by soldering, crimping or brazing at a proximal end 320A of the flexible wire 320 to the distal end 314B of the tubular member 314 as in the manner show in FIGURE 17.

Preferably, the proximal end 320A of the flexible wire 320 has a transverse cross sectional area substantially less than the smallest transverse cross-sectional area of the inner lumen 315 of the tubular member 314. In the preferred embodiment, the flexible wire 320 tapers in the distal end 320B to smaller diameters to provide greater flexibility to the flexible wire 320. However, the flexible wire may be in the form of a solid rod, ribbon or a helical coil or wire or combinations thereof.

As shown in FIGURE 17, the distal end 320B of the flexible wire 320 is secured to a rounded plug 318 of solder or braze at the distal end 322B of the coil member 322. The coil member 322 of the catheter 310 may be comprised of a helical coil 322. The coil member 322 is coaxially disposed about the flexible wire 320, and is secured to the flexible wire 320 by soldering or brazing at about the proximal end 320A of the flexible wire 320 as in the manner shown in FIGURE 17. The balloon member 316 is preferably a compliant balloon formed of a suitable elastic material such as a latex or the like. The flexible coil 322 is preferably formed of a radiopaque material such as platinum or gold. The flexible core-wire 320 and the tubular member 314 are preferably formed of a nickel-titanium alloy or stainless steel.

The catheters of the present invention are preferably provided with a coating on the outer surface, or on both the inner and outer surfaces. Suitable coatings include hydrophilic, hydrophobic and antithrombogenic coatings. Examples include heparin and TEFLON. These coatings can be applied using methods well known in the art.

Fluid Mechanics of Irrigation/Aspiration

In order to understand the design criteria of the catheter system of the present invention, it is useful to have some understanding of the fluid mechanics of the system. The effect of the pressure differential between the irrigation and aspiration openings on the emboli containment chamber was first studied. It was confirmed that as the pressure differential increased, the flow rate in the chamber increased exponentially.

Some preliminary studies demonstrated that the fluid flow through the irrigation catheter into the chamber then out through the aspiration catheter could be represented by equations for fluid flow in pipes. The basic equation for incompressible fluid flow in a pipe is based on Bernoulli's equation for steady state flow of inviscid, incompressible fluids:

$$p_1+1/2\rho V_1^2+\gamma Z_1=p_2+1/2\rho V_2^2+\gamma Z_2$$

where p-pressure, ρ-density, V-velocity, γ-specific weight, and Z-elevation. When fluid flows in a pipe or, in this case the irrigation/aspiration system within the containment chamber, the behavior of the fluid can be described by the equation:

$$\Delta p=K\rho V^2/2 \qquad let K\rho/2=k_2$$
$$\Delta p=k_2V^2$$
$$\Delta p\propto V^2$$

where K is the resistance coefficient and the fluid velocity V can be expressed in terms of fluid flow (Q) by the equation V-Q/A where A-cross sectional area. Therefore for a given irrigation/aspiration system K, A and ρ can be assumed to be constant, indicating that the square of the fluid velocity is proportional to the pressure differential between the irrigation and aspiration pressures.

The results of the initial testing clearly showed that the fluid flow through the system did behave as predicted and proved that as the change in pressure (Δp) increased the flow rate increased. The time required to remove emboli from the chamber with respect to the irrigation and aspiration pressures and the cross sectional area used for aspirating was also investigated. As expected, as the aspiration cross sectional area increased, there was a reduction in the time required to remove the emboli which was due to the corresponding fluid flow increase. The results showed that by increasing the initial Δp across the system, the flow rate increased as well, but the irrigation pressure had more effect on the flow rate than the aspiration pressure. The emboli removal was also affected by the flow rate with a shorter time being required for removal for a higher Δp and again, the higher irrigation pressure was the major factor.

There was some initial concern that pressure would build within the chamber if the configuration of the system or the change in pressure was not properly designed. However, in the studies performed, the pressure within the chamber ranged between
-7.1 to 2 psig (gauge pressure where 0 psig-atmospheric pressure) depending on the main catheter internal diameter (ID) and the Δp across the system. These results indicate that over pressurization of the chamber is not an issue in this system.

Further investigation into the fluid mechanics in the emboli containment chamber was conducted as follows. A main catheter having an occlusion balloon on its distal end was first inserted into a 4 mm ID flexible polymer tube.

A guidewire having a 4 mm inflatable occlusion balloon at its distal end was inserted through the main catheter and past the distal end of the main catheter so that a 100 mm chamber was created between the two balloons within the flexible tube. An irrigation catheter was then positioned just proximal of the guidewire balloon. The main and guidewire balloons were then inflated to isolate the chamber.

A pump was connected to an irrigation port on the irrigation catheter using a stop cock, and a pressure gauge was connected inline with the pump output line. A 60 cc syringe was connected to an aspiration port on the main catheter to provide aspiration pressure or vacuum. A vacuum/pressure gauge was connected inline with the aspiration line to the syringe. A 100 ml beaker of fluid (8.5 g/L sodium chloride solution or water) to be used in the test was then provided. The pump was operated until the chamber was filled with fluid and all the air was out of the irrigation and aspiration catheters.

A summary of the apparatus used in testing is shown below in Table 1:

Table 1: Test Apparatus Dimensional Breakdown

Main Catheter ID/OD:	.065/.086	
Irrigation Catheter ID/OD:	.038/.046	
Asp. X-sectional Area:	.0017	in^2
Chamber length:	10	cm
Chamber ID:	.4	cm
Chamber Volume:	1.3	cc

With the input line to the pump in the filled beaker, the pump was operated and adjusted to the desired pressure. Twenty-five cc of fluid was measured and placed into an empty beaker, and the input line to the pump was placed into the beaker. The stop cock to the aspiration catheter was closed, and the plunger on the 60 cc syringe was pulled back until the desired vacuum was obtained. The pump was then turned on, and simultaneously, the stop cock to the aspiration port was opened and a timer was started. When the desired time had passed, the pump was turned off and the fluid remaining in the beaker and the fluid collected in the 60 cc syringe was measured.

A two level factorial design with two replications was used to determine the effect irrigation pressure and aspiration vacuum had on the flow rate through the system via the 4 mm x 100 mm tubular chamber (see Table 2).

Table 2: Factors and levels

Factor	Low Level	High Level
Irrigation Pressure	5 psig	30 psig
Aspiration Pressure	-10 in-Hg	-25 in-Hg

The results of the testing are shown below in Tables 3 and 4.

Table 3: Flow Data Using a Saline Solution for Irrigation

Initial* δP (psi)	Irr Initial Press (psig)	Asp Initial Press (in-Hg, gauge)	δVin		δVout		δVin-δVout		Time		ASP Flow Rate	
			mean (cc)	stdev (cc)	mean (cc)	stdev (cc)	mean (cc)	stdev (cc)	mean (sec)	stdev (sec)	mean (cc/min)	stdev (cc/min)
9.9	5	-10	4.2	.20	4.1	.23	.2	.12	53.7	1.46	4.6	.15
17.3	5	-25	8.3	.58	8.4	.35	-.1	.23	54.8	.37	9.2	.33
19.9	15	-10	9.1	.12	8.8	.20	.3	.31	53.2	1.04	9.9	.41
27.3	15	-25	10.5	.46	8.4	.53	2.1	.42	55.6	2.45	9.1	.65
34.9	30	-10	10.1	.12	9.3	9.27	.8	.40	53.7	.58	10.4	.36
42.3	30	-25	10.2	.40	9.1	.61	1.1	.23	53.6	.58	10.2	.57

Table 4: Flow Data Using Water for Irrigation

Initial* δP (psi)	Irr Initial Press (psig)	Asp Initial Press (in-Hg, gauge)	δVin		δVout		δVin-δVout		Time		ASP Flow Rate	
			mean (cc)	stdev (cc)	mean (cc)	stdev (cc)	mean (cc)	stdev (cc)	mean (sec)	stdev (sec)	mean (cc/min)	stdev (cc/min)
9.9	5	-10	7.3	.30	6.6	.38	.7	.15	57.7	2.23	6.9	.15
17.3	5	-25	14.4	2.09	13.4	1.43	1.0	2.15	56.1	.46	14.4	1.47
19.9	15	-10	12.1	4.22	9.3	.58	2.8	3.64	56.0	.57	10.0	.56
27.3	15	-25	10.5	.50	9.9	.61	.6	.53	54.6	2.81	10.9	.78
34.9	30	-10	10.9	1.01	10.1	.50	.7	.76	55.5	3.41	11.0	.15
42.3	30	-25	9.8	.35	10.0	.20	-2	.20	53.1	.99	11.3	.15

* Pressure equalization after max 45 sec. As δP increases, the time to equalize increases

δP is the pressure differential between the irrigation bag and the vacuum in the aspiration syringe

V = volume and n=3 unless otherwise noted

The irrigation pressure was varied between 5 and 30 psig with the aspiration pressure varying between -10 and -25 in-Hg. The results show that there was little difference between the use of the saline solution and the use of water. The lowest flow rate of 4.6 cc/min was obtained for a 5 psi irrigation pressure and a -10 in-Hg aspiration pressure ($\delta p = 9.9$ psi). The highest flow rates were obtained when a 30 psi irrigation pressure was used with rates of 10.4 and 10.2 cc/min for an aspiration pressure of -10 ($\delta p = 34.9$ psi) and -25 in-Hg ($\delta p = 42.3$ psi) respectively.

The results of this two level factorial design supported the results obtained in earlier studies: that as the δp across the system increases, the flow rate increases exponentially.

The results were consistent with Bernoulli's equations for flow in a tube in that the fluid velocity is proportional to the square root of the pressure differential between the two points assuming a constant fluid density and losses. When the flow rate was plotted against δp an exponential trend with an $R^2 = .7154$, the results support the proportional relation between pressure and the fluid flow rate expressed in equation 2 (see FIGURE 19).

Analysis of the data produced an extremely significant model with an adjust $R^2 = .994$ (see Table 5). Each of the main factors as well as the interaction between the irrigation and aspiration pressure were highly significant with a $p < .0000$.

Table 5: Data Analysis and Model for Flow Rate (solution: saline)

Adjusted R^2 .994

Standard Error .227

Mean Abs. Error .1278

	Coefficient	Error	Factor*	p-value
Flow Rate (cc/min) =	8.6	± .0654		
	3.367	± .1309	Irrigation	.0000
	-2.2	± .1309	Aspiration	.0000
	2.37	± .1309	Irr* Asp	.0000

*Use coded values between -1 and 1 to determine predicted flow rates

The analysis of the interaction between the irrigation and aspiration pressure showed that by using a lower aspiration pressure of -25 in-Hg the effect of the irrigation pressure can be minimized (see FIGURE 20). The increase in the flow rate between 5 and 30 psig was 1.0 cc/min for an aspiration pressure of -25 in-Hg, whereas the increase was significantly higher, 5.6 cc/min, when an aspiration pressure of -10 in-Hg was used. Another advantage of using the lower aspiration pressure was that it took longer for the pressure to equalize as measured by the aspiration pressure gauge thus a higher flow rate was sustained over a longer period of time.

The tubular chamber used in this study was 4 mm x 100 mm which contained a volume of 1.3 cc; therefore for the worst case flow rate of 4.6 cc/min (IP = 5 psig, AP = -10 in-Hg) the fluid is exchanged approximately 3.5 times taking approximately 17 seconds for each exchange. The fluid collection in one minute is 9.2 cc for an

IP=5 psig and an AP=-25 in-Hg, which would flush the 1.3 cc chamber in approximately 7.5 seconds or 8 times per minute.

This understanding of the fluid mechanics inside the emboli containment chamber resulting from the testing described above lead to the development of the method of the present invention, which provides efficient irrigation and aspiration for removal of emboli and debris inside the body following treatment of an occluded vessel.

Emboli Containment Methods of the Present Invention

The operation and use of the emboli containment system utilizing the catheters of the present invention for treating occluded vessels will now be described in connection with an occlusion formed by a stenosis in a carotid artery, as illustrated in FIGURES 18A-H. It should be noted that this application is merely exemplary, and that the method of the present invention can be used in other blood vessels in the body as well. The word "proximal" as used herein refers to the portion of the catheter closest to the end which remains outside the patient's body, while "distal" refers to the portion closest to the end which is inserted into the body.

A guiding catheter (not shown) is first introduced into the patient's vasculature through an incision in the femoral artery in the patient's groin. The guide catheter is advanced through the artery into the aorta of the heart of the patient and into the ostium of the carotid artery to be treated, where it remains throughout the procedure if needed. Fluoroscopy is typically used to guide the catheter and other devices to the desired location within the patient. The devices are typically marked with radiopaque markings to facilitate visualization of the insertion and positioning of the devices.

Referring now to FIGURE 18A, a main catheter 410 having a distal attached occlusive device 412, in this example an inflatable balloon, is advanced into the ostium of the carotid artery and into the lumen 418 of the vessel 414. The main catheter 410 with the occlusive device 412 thereon is advanced until the device 412 is just proximal to the stenosis 406. The device is activated, i.e. the balloon 412 is then inflated, to occlude the vessel 414. The inner catheter, in this example a guidewire 400, having an occlusive device 402, in this example an inflatable balloon, at its distal end 404 is next delivered through the main catheter 410. The occlusive device 402 is positioned just distal to the occlusion 406. The occlusive device is activated, i.e., the balloon 402 is inflated to create an isolated chamber within the vessel which surrounds the occlusion. The balloons 402, 412 are each progressively inflated until they engage the side wall of the vessel 414 to occlude the lumen 418. Preferably, the distance between the proximal end of the occlusive device on the guidewire 404 and the distal tip of the occlusive device on the main catheter 416 should be approximately 5-10 cm. Advantageously, the present invention allows for the creation of a treatment and containment chamber whose length can be easily adjusted to isolate a specific area within a blood vessel. As soon as both balloons 402, 412 are inflated, a working space 422 is provided between the balloons 402, 412, so that therapeutic procedures can be undertaken to remove or reduce the occlusion 406 in the space between the balloons 422, without risk of unwanted particles or emboli escaping into the blood stream. The inner catheter 400 and the main catheter 410 with their attached distal occlusive devices 402, 412 are therefore used to create a chamber 422 surrounding the occlusion 406, and act to contain the emboli and debris 424 resulting from the treatment of the occlusion 406 as illustrated in FIGURE 18C.

Alternatively, a guide catheter or angiography catheter can first be delivered to the site of the occlusion. The inner catheter is inserted through the guide or angiography catheter, and positioned within the patient. The guide or angiography catheter is removed, and the main catheter is inserted over the inner catheter into position proximal to the occlusion. The occlusive device at the distal end of the main catheter is activated, the occlusive device on the inner catheter is put into position distal to the occlusion and activated, and the procedure continues as described above.

Alternatively, the main catheter can be delivered directly to a position just proximal to the occlusion, without use of a guide or angiography catheter. The inner catheter is then delivered through the main catheter as described above.

In another alternative embodiment of the present invention, the inner catheter can be delivered first through the guide catheter. The occlusive device on the distal end of the inner catheter is positioned distal to the occlusion. The main catheter is introduced over the inner catheter and advanced into the ostium of the carotid artery and into the lumen of the vessel. The main catheter is advanced until the balloon is just proximal to the occlusion. The intermediate catheter is then delivered into the chamber to provide appropriate therapy. The occlusive devices on the distal ends of the inner and main catheters are activated, to create a treatment and isolation chamber surrounding the occlusion. This method can be used when the physician determines that the risk of crossing the occlusion prior to activation of the proximal occlusive device is minimal.

Referring now to FIGURE 18B, once the chamber has been created around the occlusion, an intermediate catheter 420 is delivered to the site of the occlusion 406. In the example illustrated in FIGURES 18A-F, the intermediate catheter 420 is a therapy catheter having an angioplasty balloon on its distal end. The intermediate catheter 420 is delivered to the site of the occlusion 406 as shown in FIGURE 18B.

The term "therapy catheter" is meant to include any of a number of known devices used to treat an occluded vessel. For example, a catheter carrying an inflatable or mechanically activated balloon for use in balloon angioplasty, as is used in this example, can be delivered to dilate the stenosis. Thermal balloon angioplasty includes the use of heat to "mold" the vessel to the size and shape of the angioplasty balloon. Similarly, an intravascular stent can be delivered via a balloon catheter and deployed at the site of the stenosis to keep the vessel open. Cutting, shaving, scraping, or pulverizing devices can be delivered to excise the stenosis in a procedure known as atherectomy. A laser or ultrasound device can also be delivered and used to ablate plaque within the vessel. Various types of rheolitic devices could be used. Various thrombolytic or other types of drugs can be delivered locally in high concentrations to the site of the occlusion. It is also possible to deliver various chemical substances or enzymes via a catheter to the site of the occlusion to dissolve the obstruction. A combined aspiration and therapy catheter can also be used. The term "therapy catheter" encompasses these and other similar devices.

Referring now to FIGURE 18D, after the balloons 402 and 412 are properly inflated, and the therapy catheter 420 in place, therapy begins. For emboli containment systems featuring balloon dilatation treatment, it is desired to compress the plaque or material forming the 406 to provide a larger passageway through the vessel. Thus, a balloon angioplasty catheter 420 is positioned such that the distal end with the balloon 426 thereon is at the site of the occlusion 406. When the balloon 426 has been properly positioned within the 406, the balloon 426 is inflated with a suitable inflation medium, as for example a radiopaque liquid. The angioplasty balloon 426 can be inflated to the desired pressure to cause compression of the plaque of the occlusion 406 against the sidewall of lumen 414 by the application of appropriate inflation pressure, as shown in FIGURE 18D. As in conventional angioplasty procedures, the balloon 426 can be formed of a non-elastic relatively non-compliant material so that appropriate pressures, such as 10-15 atmospheres, can be created within the balloon to apply compressive forces to the vessel 414 without danger of rupturing the vessel 414. It should be appreciated that the non-elastic capabilities can also be achieved by a composite elastic material.

After appropriate therapy has been performed and the occlusion 406 has been removed or lessened using any of the methods and apparatus described above, the therapy balloon 426 is deflated as illustrated in FIGURE 18E. A source of irrigation fluid (not shown) is connected to the adaptor 434 located at the proximal end of the therapy catheter 420, and a source of aspiration pressure (not shown) is connected to an adaptor 436 located at the proximal end of the main catheter 410, as illustrated in FIGURE 18F. Preferably, the source of irrigation fluid is a bag of normal saline, typically used in intravenous infusion. The source of aspiration pressure is preferably a syringe. After the source of irrigation and aspiration are connected, irrigation and aspiration are begun. Irrigation fluid is provided through the inner pathway between the therapy catheter 420 and the guidewire 400, while aspiration is provided through the outer pathway between the therapy catheter 420 and the main catheter 410 as shown by the small arrows in FIGURE 18F. Of course it is to be understood that irrigation fluid could be provided through the outer pathway while aspiration is provided through the inner pathway. In either case, suitable pressures are provided to ensure that the change in pressure inside the chamber does not damage the vessel. The change in pressure as fluid flows into and out of the chamber should not exceed about 50 psi. Suitable pressures range from approximately -10 to -30 in-Hg aspiration pressure, and about 5 to 30 psig irrigation pressure. Note that these pressures are measured at the proximal end of the catheters.

In an alternative embodiment not shown, after therapy has been performed to remove or reduce the occlusion the therapy catheter is removed from the emboli containment system, and an irrigation catheter is delivered to the emboli containment chamber. The irrigation catheter is inserted through the main catheter lumen. The main lumen of the irrigation catheter can ride over the inner catheter, or the inner catheter can be positioned in a separate lumen adjacent to the main lumen. The distal end of the irrigation catheter is positioned just proximal the distal occlusion balloon, preferably approximately 1-2 cm from the balloon. As noted above, the irrigation and main catheter are sized such that the irrigation catheter can pass through the main catheter lumen and the annulus or outer pathway between the main catheter lumen and the irrigation catheter is large enough to allow aspiration of the blood and debris through it. Irrigation fluid is provided through the inner pathway between the inner catheter and the irrigation catheter. Alternatively, an aspiration catheter, a combined irrigation/aspiration catheter, or similar debris removing device such as a rheolitic device, can be used as the intermediate catheter. In this embodiment of the invention, the aspiration catheter is delivered in the same manner as described above for the irrigation catheter. Aspiration then occurs through the inner pathway, while irrigation is provided through the outer pathway.

Once the desired catheters are properly positioned, irrigation and aspiration are performed. The irrigation fluid and aspiration pressure are delivered in such a way as to ensure that the change of pressure within the chamber is below about 50 psi to avoid damaging the vessel. The irrigation fluid, preferably normal saline solution, is preferably delivered at a pressure of from about 5 psi to about 50 psi; 5 psi is preferred. The aspiration pressure is preferably between about -5 and -30 in-Hg, and more preferably is about -20 in-Hg. Again, these pressures are measured from at the proximal end of the catheters. The irrigation and aspiration can be delivered simultaneously, continuously, or delivery can be pulsed, or one can be delivered continuously while the other is delivered in a pulsed fashion. The user can determine the best method of delivery to provide optimized flow, turbulence, and clearance within the chamber.

Referring again to FIGURE 18F, it is preferable that the inflation pressure within the distal occlusion balloon 402 is maintained at a level greater than the pressure in the chamber and the jet created by irrigation to avoid the leakage of fluid and debris past the distal occlusion balloon 402. Similarly, the inflation pressure in the proximal occlusion balloon 412 should be maintained at a level greater than the pressure in the chamber and the aspiration pulsation to avoid having fluid aspirated from behind the balloon 412 and possibly aspirating the balloon 412 itself. Again, the irrigation and aspiration pressures provided are such that the change in pressure during fluid flow into and out of the vessel does not damage the vessel. The change in pressure is preferably no greater than about 50 psi.

In another embodiment of the present invention, after the therapy catheter is removed, the aspiration catheter is delivered such that its distal end is positioned approximately 1-2 cm from the distal occlusive device. The proximal occlusive device is then deactivated, to allow blood flow into the chamber. This blood flow is used as irrigation flow. The blood, acting as irrigation fluid, is aspirated together with particles and debris through the aspiration catheter. This eliminates the need for a separate source of irrigation fluid. In this embodiment, it is preferred that the blood flow rate in the vessel is greater than about 100 cc/min, and flow rates of 60-80 cc/min are preferred. This method is illustrated in FIGURE 18G.

In yet another embodiment, illustrated in FIGURE 18H, after the therapy catheter is removed, the proximal occlusive device is deactivated, allowing blood flow into the chamber. The blood, acting as irrigation fluid, is aspirated together with particles and debris through the opening in the main catheter. This eliminates the need for a separate aspiration catheter and a separate source of irrigation fluid, thereby reducing the time necessary to complete the procedure.

Aspiration and irrigation are continued until particles and debris 424 are removed from the chamber 422, then the irrigation, aspiration, or the therapy catheter 420, is removed. First the distal 402 and then the proximal 412 occlusion balloons are deflated, and the guidewire 400 and main catheter 410 are removed. Finally, the guide catheter is removed, and the incision in the patient's femoral artery is closed.

Although the foregoing detailed description has described several embodiments of the present invention, it is to be understood that the above description is illustrative only and not limiting of the disclosed invention. It will be appreciated that certain variations of the present invention may suggest themselves to those skilled in the art. Thus, the spirit and scope of this invention are to be limited only by the claims which follow.

WHAT IS CLAIMED IS:

1. A catheter system, comprising:

a hollow inner catheter having a proximal end and a distal end;

an occlusion device mounted on the distal end of the inner catheter; and

a main catheter sized to receive the inner catheter such that an outer fluid pathway is formed therebetween for irrigation or aspiration, said main catheter having an occlusion device mounted on a distal end which cooperates with the occlusion device on the inner catheter to form a chamber therebetween, and the main catheter having a dedicated irrigation/aspiration port to permit simultaneous irrigation and aspiration within the chamber.

2. The system of Claim 1, wherein said inner catheter comprises a guidewire.

3. The system of Claim 1, further comprising an intermediate catheter, wherein at least a portion of said intermediate catheter is positioned over said inner catheter such that an inner fluid pathway is formed therebetween and such that the intermediate catheter is slidable to a location proximal to the occlusion device on the inner catheter.

4. The system of Claim 3, wherein said intermediate catheter comprises an irrigation catheter.

5. The system of Claim 3, wherein said intermediate catheter comprises an aspiration catheter.

6. The system of Claim 3, wherein said intermediate catheter comprises a therapy catheter.

7. The system of Claim 6, wherein said therapy catheter comprises a catheter selected from the group consisting of a balloon angioplasty catheter, a stent deploying catheter, an ultrasound device, and a drug delivery catheter.

8. The system of Claim 3, wherein said intermediate catheter comprises a catheter which can both aspirate and irrigate.

9. The system of Claim 1, wherein said occlusion device on said inner catheter is an inflatable balloon.

10. The system of Claim 1, wherein said occlusion device on said main catheter is an inflatable balloon.

11. The system of Claim 9, wherein said main catheter further comprises an inflation lumen in a wall of said main catheter in fluid communication with said inflatable balloon.

12. The system of Claim 1, wherein said main catheter has an outer diameter of less than 5 mm.

13. The system of Claim 3, wherein the inner pathway and the outer pathway each have an opening at a distal end which are approximately equal in size.

14. The system of Claim 3, wherein the inner pathway and the outer pathway each have an opening at a distal end of at least about 150 micrometers.

15. The system of Claim 3, wherein the inner pathway and outer pathway comprise each have an opening at a distal end of at least about 500 micrometers in diameter.

16. The system of Claim 1, further comprising at least one additional inner catheter having an occlusion device mounted on a distal end sized fit slidably within said main catheter.

17. The system of Claim 3, wherein said intermediate catheter further comprises a main lumen and a separate lumen adjacent said main lumen sized to received said inner catheter slidably therein.

18. The system of Claim 16, wherein said separate lumen further comprises a slit in an outside wall for insertion and removal of the inner catheter therethrough.

19. The system of Claim 3, wherein irrigation fluid is provided through said inner pathway and aspiration pressure is provided through said outer pathway.

20. The system of Claim 1, wherein the main catheter has a proximal end and the distal end of said main catheter is more flexible than the proximal end.

21. A catheter system, comprising:

a hollow guidewire having a proximal end and a distal end;

an inflatable balloon mounted on the distal end of the guidewire;

an intermediate catheter, wherein at least a portion of said intermediate catheter is positioned over said guidewire such that an inner fluid pathway is formed therebetween and such that the intermediate catheter is slidable to a location proximal to the balloon; and

a main catheter sized to receive the intermediate catheter such that an outer fluid pathway is formed therebetween for irrigation or aspiration, said main catheter having an inflatable balloon mounted on a distal end which cooperates with the balloon on the inner catheter to form a chamber therebetween, and the main catheter having a dedicated irrigation/aspiration port to permit simultaneous irrigation and aspiration within the chamber.

22. The system of Claim 20, wherein the inner pathway and the outer pathway each have an opening at a distal end which are sized to balance fluid flow.

23. The system of Claim 20, wherein the inner pathway and the outer pathway each have an opening at a distal end of at least about 150 micrometers.

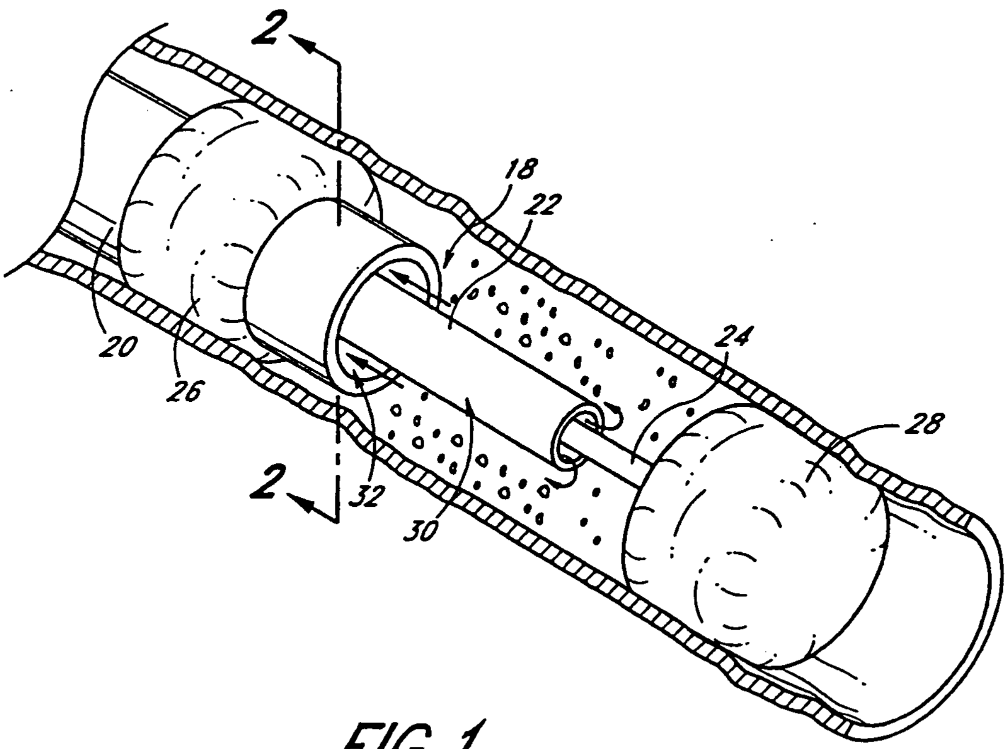


FIG. 1

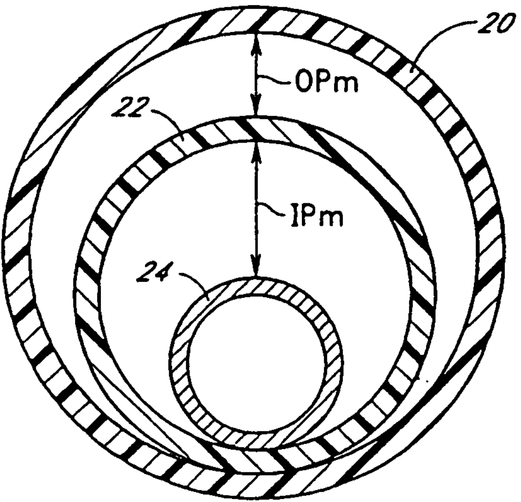


FIG. 2

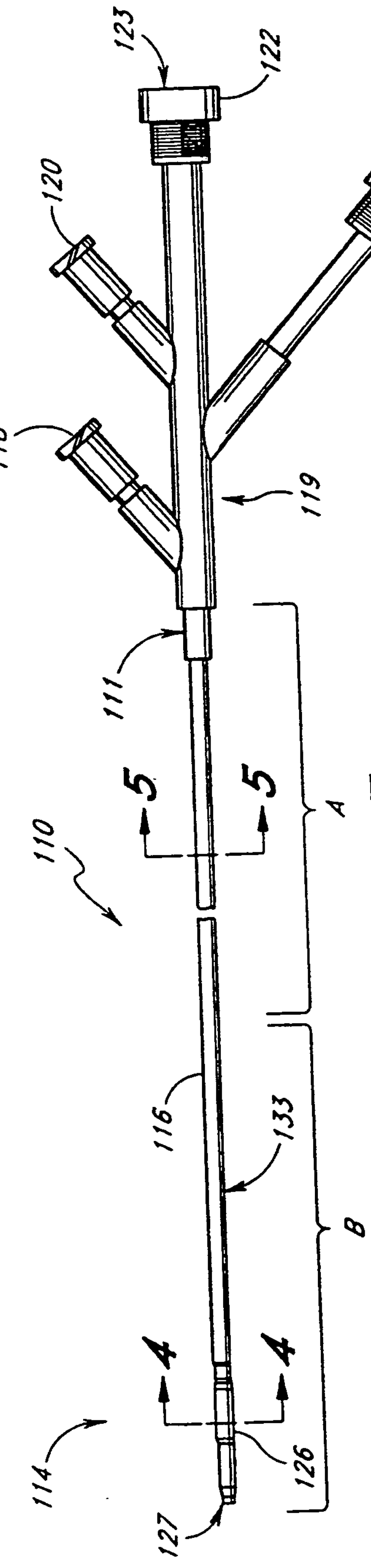


FIG.3

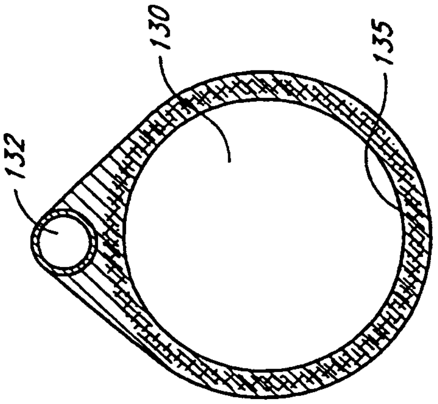


FIG.5

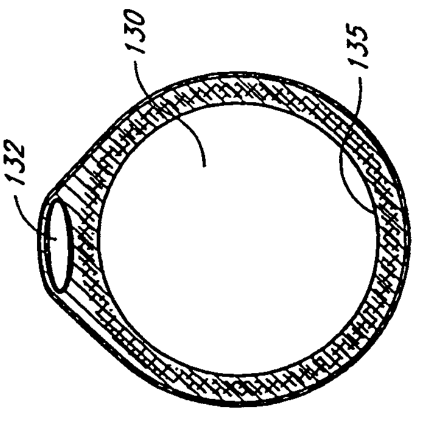


FIG.4

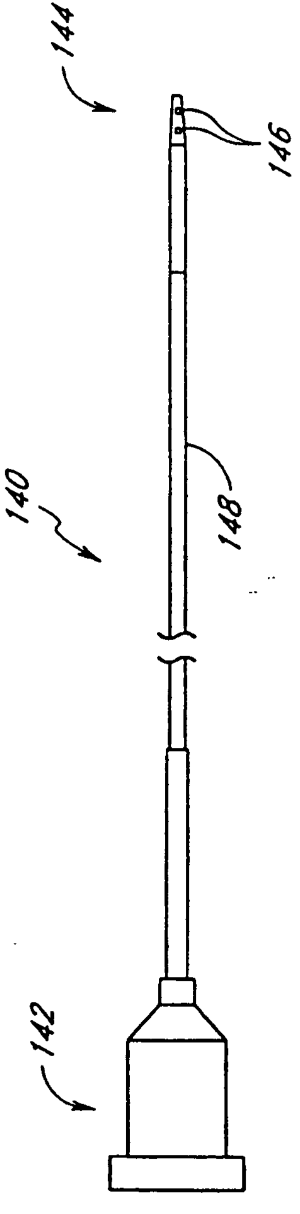


FIG. 6

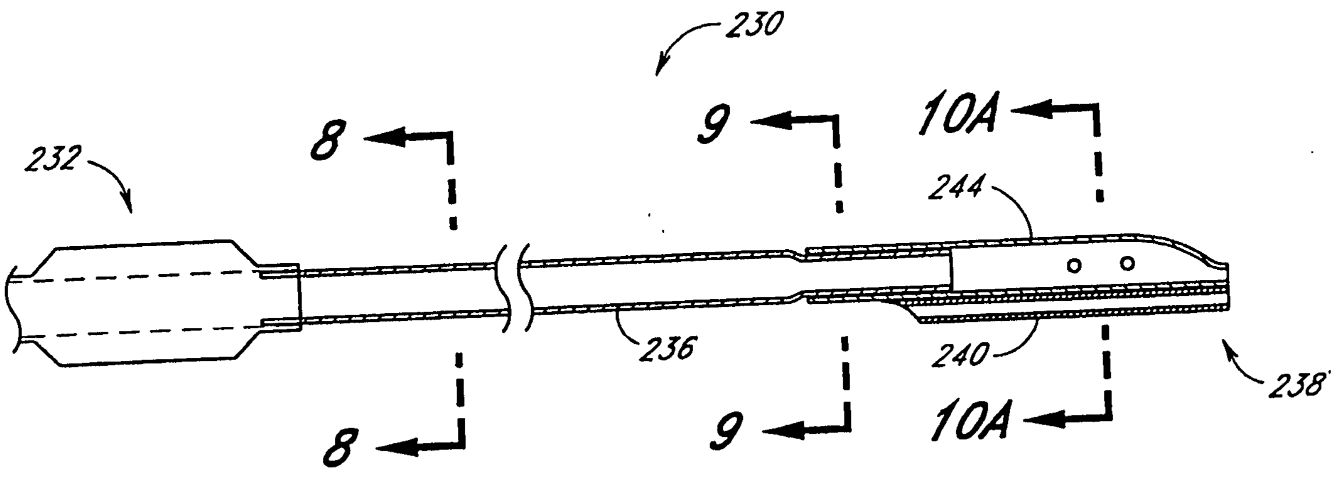


FIG.7

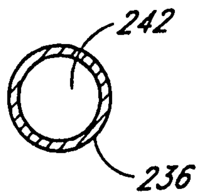


FIG.8

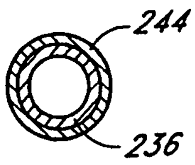


FIG.9

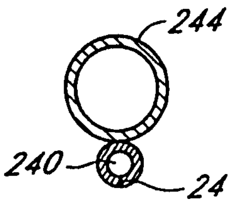


FIG.10A

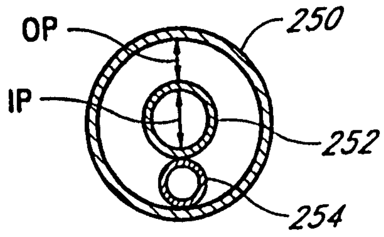


FIG.10B

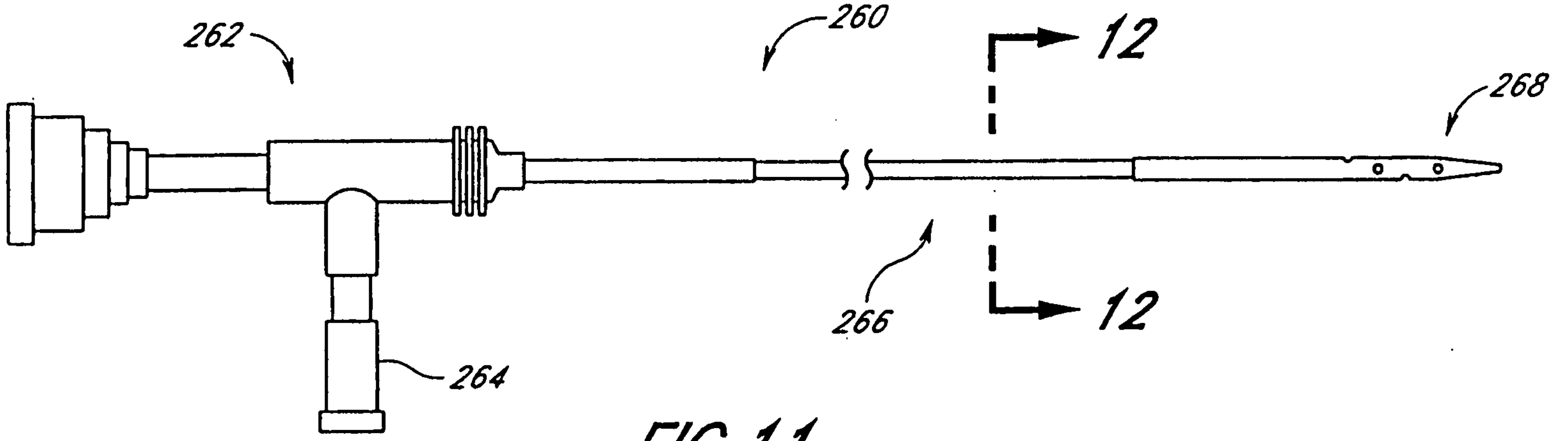


FIG. 11

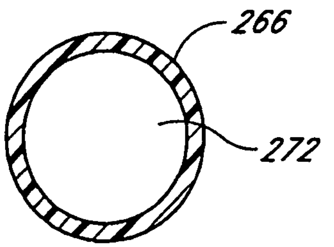


FIG. 12

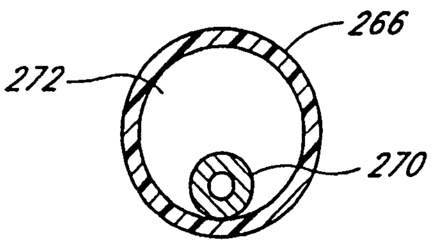


FIG. 13

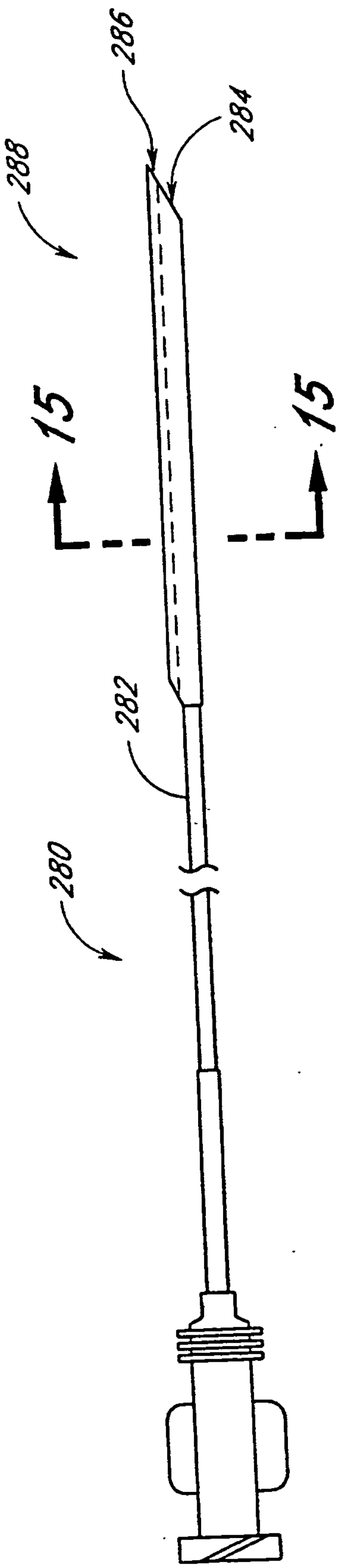


FIG.14

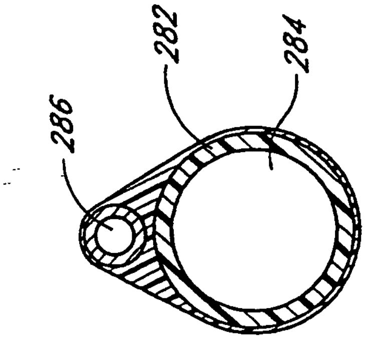


FIG.15

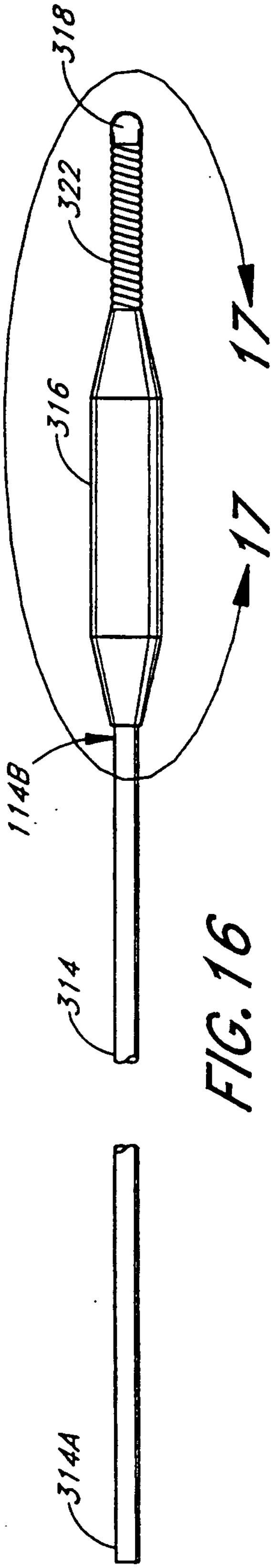


FIG. 16

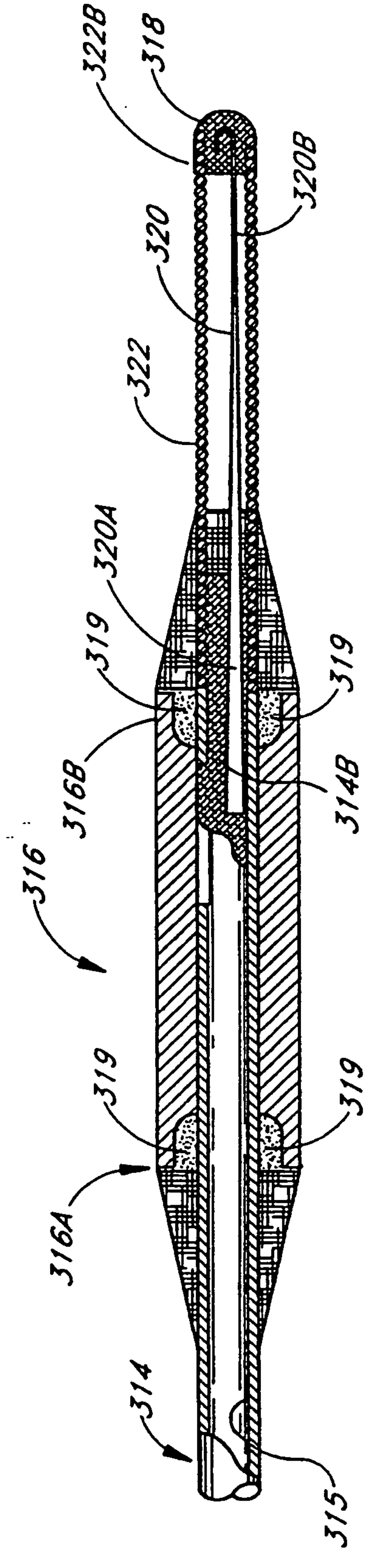


FIG. 17

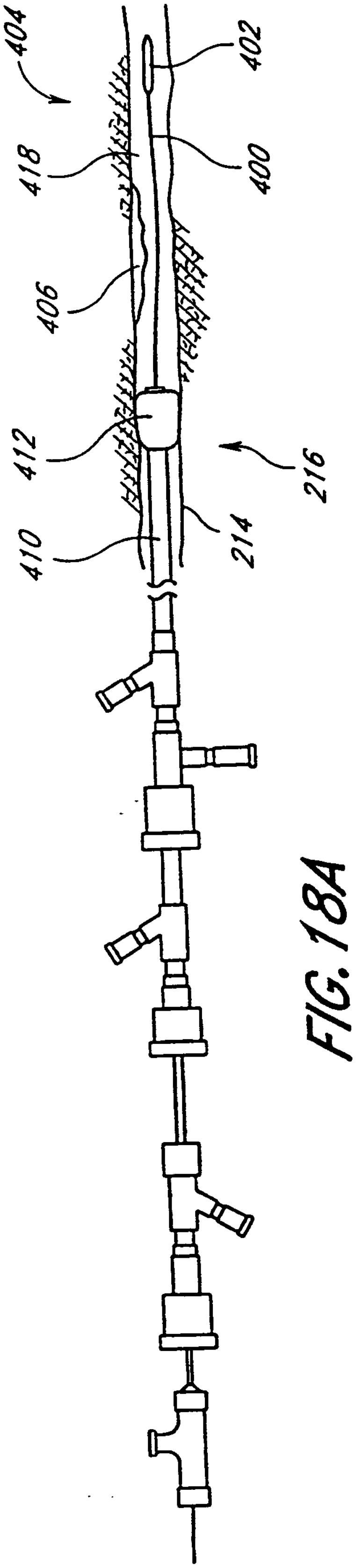


FIG. 18A

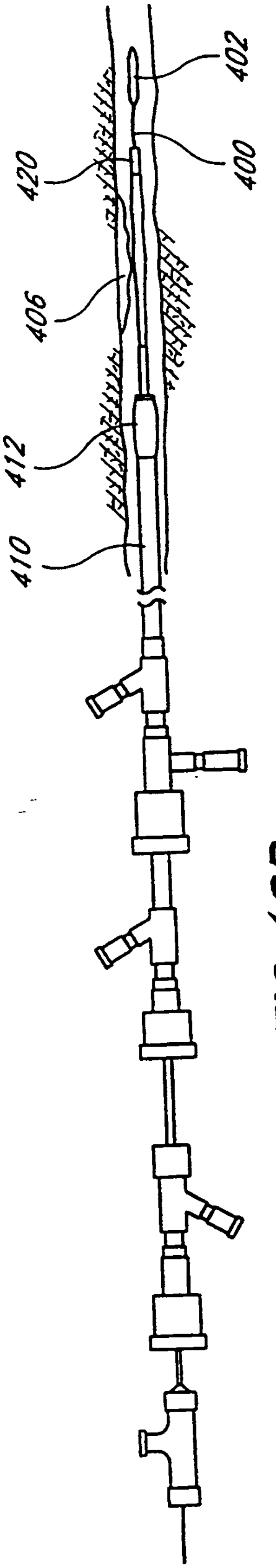


FIG. 18B

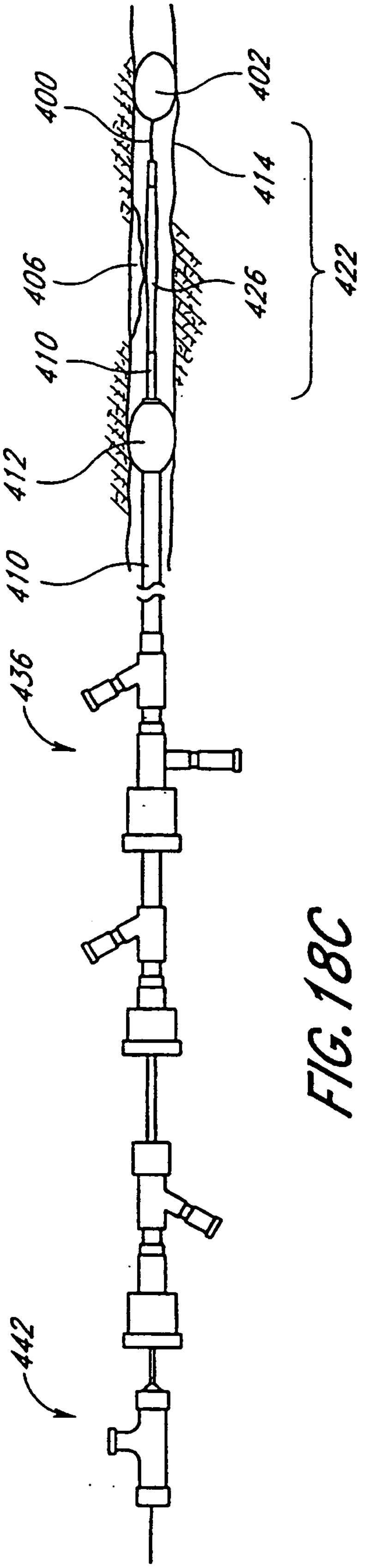


FIG. 18C

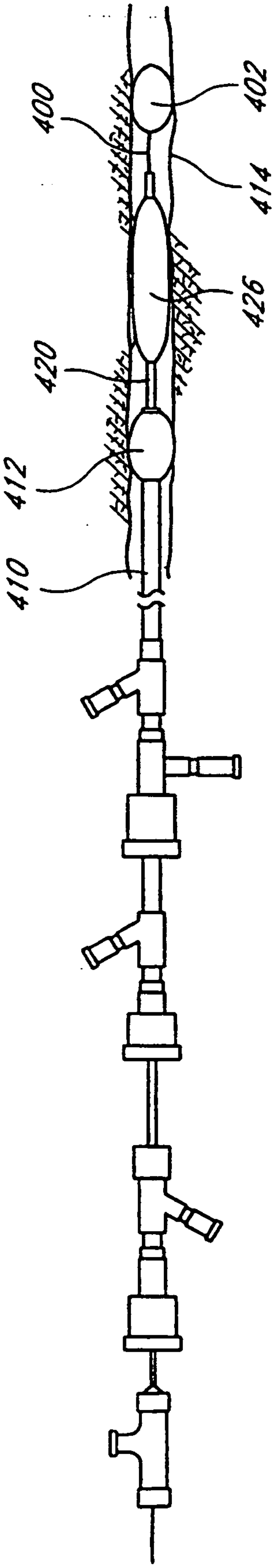


FIG. 18D

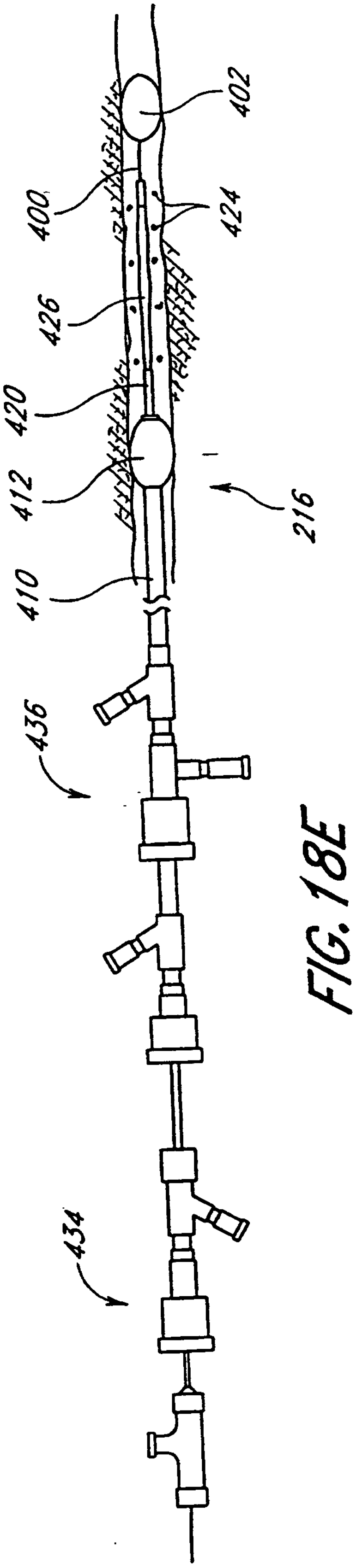


FIG. 18E

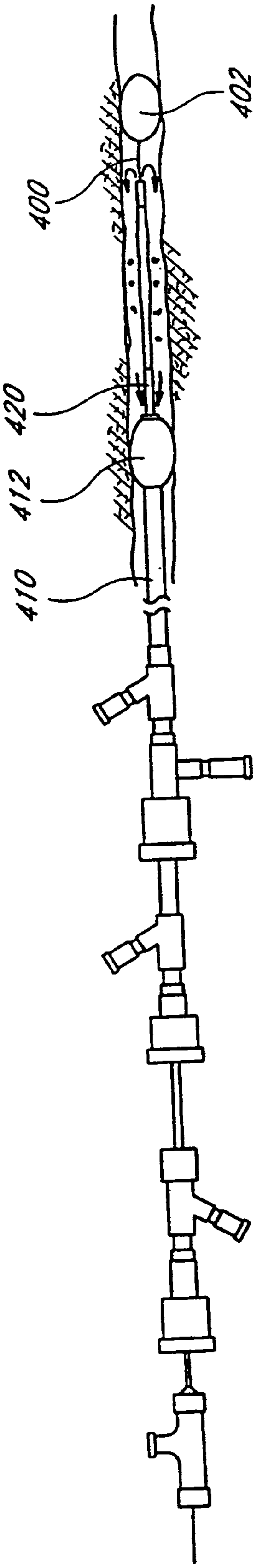


FIG. 18F

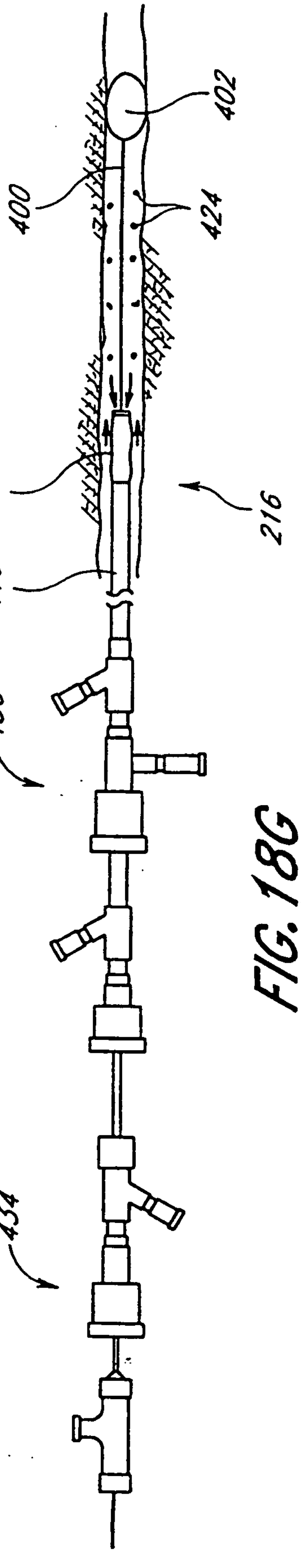


FIG. 18G

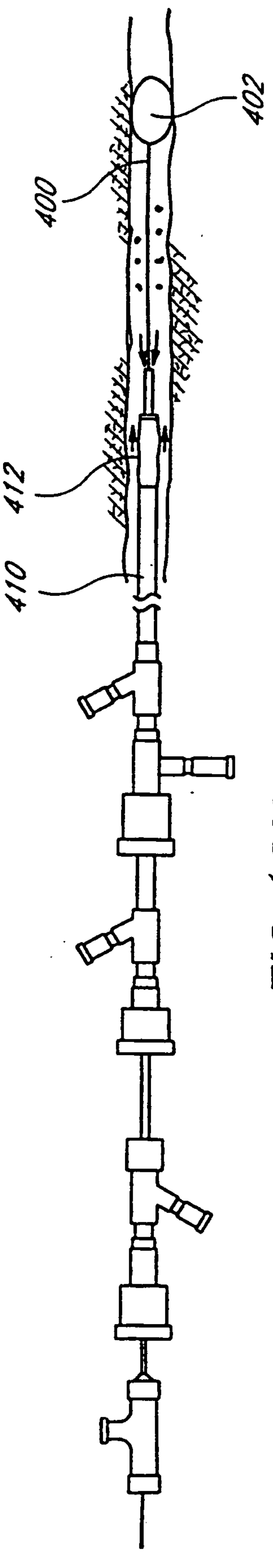
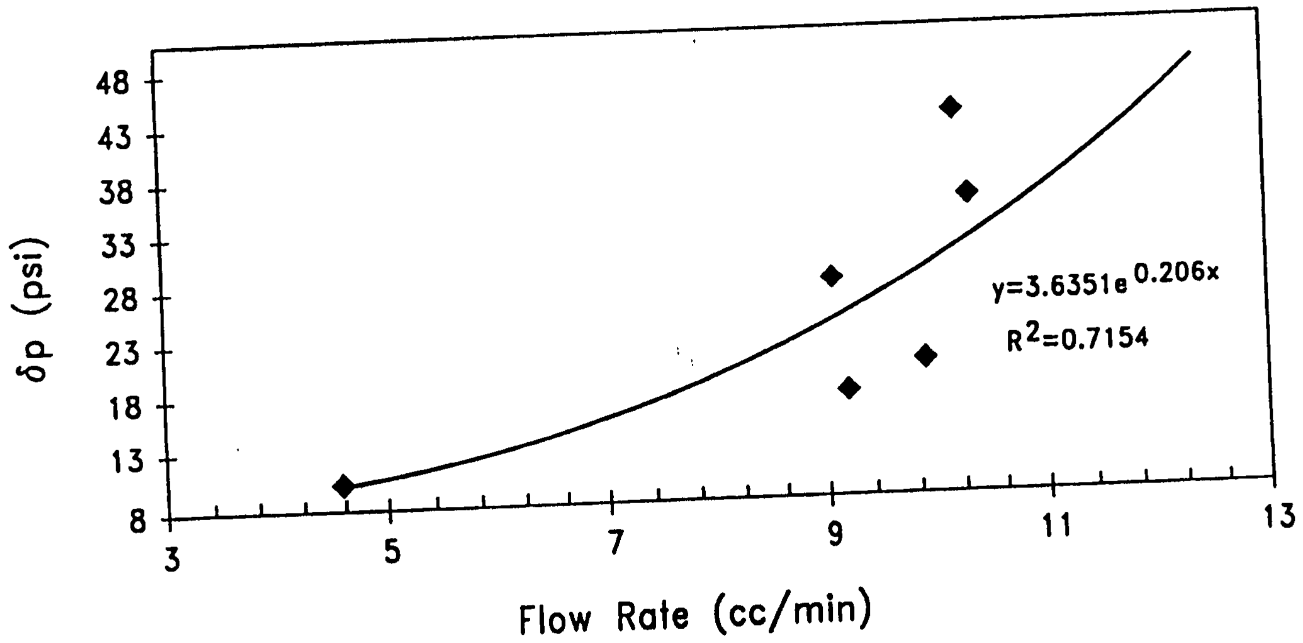
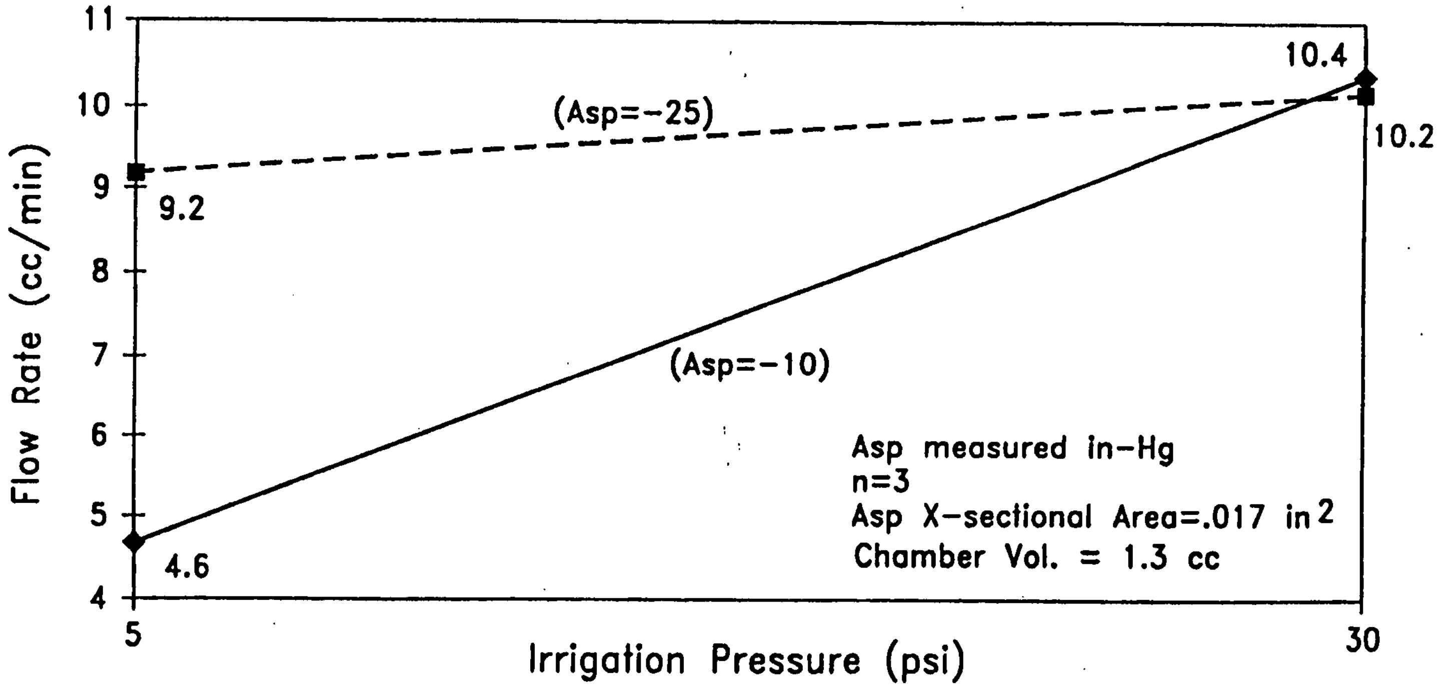


FIG. 18H



Flow Rate vs δp

FIG. 19



Flow Rate Interaction Plot Between
Irrigation and Aspiration Pressures

FIG.20

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/04485

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00 A61M25/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 09024 A (TECHNOLOGY DEV CENTER) 6 April 1995	1-4,6,7,9-11,16,19
Y	see the whole document ---	21,22
P,X	WO 97 44082 A (PERCUSURGE INC ;BAGAOISAN CELSO J (US); HA HUNG V (US); PATEL MUKU) 27 November 1997 see the whole document ---	1-3,6,7,9-12,16,20,21
X	US 5 059 178 A (YA WANG D) 22 October 1991	1-3,6,7,9-12,16,19
A	see the whole document --- -/--	21

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search 8 July 1998	Date of mailing of the international search report 17/07/1998
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Jameson, P

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 98/04485

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

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